

**EXHIBIT A**

**PROPOSED PURDUE NAS CHILDREN'S ABATEMENT CLASS COMPLAINT**

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**UNITED STATES BANKRUPTCY COURT  
SOUTHERN DISTRICT OF NEW YORK**

**In re:**

**PURDUE PHARMA L.P., *et al.*,**

**Debtors.<sup>1</sup>**

**Chapter 11**

**Case No. 19-23649 (RDD)**

**(Jointly Administered)**

**CLASS ACTION COMPLAINT IN ABATEMENT FOR MEDICAL MONITORING  
AND SURVEILLANCE AND CREATION OF A SCIENCE PANEL**

<sup>1</sup> The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014).

**EXHIBIT**

**A**

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## **I. INTRODUCTION**

1. NOW COME Plaintiffs and Putative Class Representatives Melissa Barnwell, Ashley Poe, Jacqueline Ramirez, Anita Whigham, and Lyda Haag, the Legal Guardians of Children C.G. and E.G.; P.P.; R.R., J.C.; and E.V. respectively, on behalf of themselves solely in their capacity as legal guardians and on behalf of all other similarly situated legal guardians, who hereby file their Class Action Complaint against Debtors. In support thereof, Plaintiffs state as follows.

2. This nationwide class action complaint presents the Court with a profound and unique opportunity to salvage funding from the ashes of the Purdue corporate downfall to abate an ongoing tragedy visited upon hundreds of thousands of America's infants and children, who, through no fault of their own, were diagnosed at birth with opioid-related Neonatal Abstinence Syndrome (NAS) (the "NAS Children").<sup>2</sup> Plaintiff Legal Guardians (the "Guardians") seek relief solely in their capacity as Legal Guardians and on behalf of all other Legal Guardians similarly situated (the "Guardian Putative Class") for the following: creation of an abatement trust that will fund ongoing medical monitoring and surveillance of the NAS Children, medical and developmental referral, provision of training and information for the Legal Guardians, a nationwide registry for NAS Children, and the convening and oversight of a Science Panel for purposes of epidemiological studies of the NAS Children at issue in this Complaint so that the implications of the NAS Childrens' additional risk of disease and injury may be properly addressed during the administration of the Science Panel.<sup>3</sup> This equitable abatement relief<sup>4</sup> is all medically

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<sup>2</sup> NAS refers to the diagnosis of opioid dependence of an infant at birth.

<sup>3</sup> Alternatively, the Legal Guardians seek additional and further compensatory damages on behalf of themselves and the putative class members.

<sup>4</sup> As discussed herein, the relief shall include other and further relief in equity, including, but not limited to, disgorgement and/or recovery arising out of unjust enrichment, and all other and further

necessary and arises because the Guardians and the Guardian Putative Class has an absolute duty of care for symptomatic NAS Children (over whom they also have dominion). The Guardians and the Guardian Putative Class were injured as a result of Defendant Debtor Purdue and its co-conspirators' violations of RICO, negligence, negligence per se, civil conspiracy arising out of tort, violations of New York Bus. Law §§ 349 and 350, and acts giving rise to an independent legal claim for medical monitoring and surveillance. The damages caused by these injuries will be abated by the relief requested.

3. Further, the requested abatement relief is viable only on a class-wide, non-individual basis. Efficacious relief requires that *all* similarly situated NAS Children and their Guardians be enrolled in a comprehensive and uniform monitoring and surveillance plan with the class-wide resulting data driven into the supervisory Science Panel so that it may study and inform itself according to scientific and medical principals which require robust data sets and then make care recommendations for the NAS Children as a result. There can be no Science Panel convened for a single NAS Child, and certainly no epidemiological studies from a data set of "1." Only the rising tide of a class-wide monitoring and surveillance protocol and a supervising Science Panel can lift these boats. **This generation of Americans is not yet lost, but absent an abatement, it will be. Time is of the essence, and the Court must act decisively and come to the Legal Guardians' aid.**

4. Like tens of thousands of legal guardians of infants and children across the United States, Plaintiff Legal Guardians have the direct, non-collateral, and non-delegable duties to care

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relief to which Plaintiffs and the putative class members have shown themselves to be justly entitled

for NAS Children who were born addicted to opioids<sup>5</sup> and diagnosed with NAS at or near birth. NAS is a clinical diagnosis, and “a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy.”<sup>6</sup> Prenatal exposure to opioids necessarily results in adverse medical and developmental impacts to the NAS Children<sup>7</sup> with which their Legal Guardians must contend and care. *Indeed, there is no issue of dose, exposure, or differential diagnosis for putative class members as all NAS Children in the class received an objective diagnosis of NAS at birth.* Their diagnosis was based on objective scientific criteria (test results at birth that can be mechanically determined) and there is ***only one cause: in utero exposure to opioids.*** To be clear, the dose-response relationship necessarily establishes causality within a medically diagnosed population where there is no other source of causation, as is the case for the NAS Children in the care of the Guardians and the Guardian Putative Class.

5. In addition to the illegal and criminally over-supplied secondary, diversionary market of pharmaceutical opioids that flooded the United States and insured the nefarious and planned addiction of Americans (which was caused by the acts of the Defendant Debtor Purdue

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<sup>5</sup> By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al. *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Am J Public Health. 2014 Feb; 104(2):52-9. Similarly, the number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population. Califf RM, et al. *A Proactive Response to Prescription Opioid Abuse*, N Engl J Med. 2016 Apr 14; 374(15):1480-5

<sup>6</sup> Prabhakar Kocherlakota, *Neonatal Abstinence Syndrome*, 134(2) Pediatrics 547, 547-48 (2014), available at <http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf>.

<sup>7</sup> Indeed, there is no issue of dose or exposure for putative class members as all NAS Children in the class received an objective diagnosis of NAS at birth. Where there is such a diagnosis (which is itself based on objective scientific criteria and has only one cause), the dose or exposure was necessarily sufficient to cause the objectively observable result.

and its co-conspirators), the birth mothers of the NAS Children were also medically prescribed Purdue and/or its co-conspirators' opioids.

6. Purdue has always been one of the prominent opioid manufacturers and, equally, one of the most notorious; it is a member of a small group of corporations to have company executives face criminal prosecution, only to evade conviction through settlement. However, Purdue did not create a generation of NAS children by itself. As detailed herein, Purdue acted jointly and in concert with the non-Defendant RICO Marketing Claim and RICO Supply Chain Claims co-conspirators to provide hundreds of millions of highly addictive opioids to unsuspecting physicians and patients while simultaneously ignoring thousands of births each year of dependent, innocent children who now significant additional risks beyond their diagnosis of NAS. Purdue, as set forth below, is jointly and severally liable for the conditions that necessitate the abatement relief requested herein.

7. The Opioid Crisis in America began on Purdue's doorstep. Its new drug OxyContin was approved in 1996 with a 80mg dose. Only four years later, Purdue sought and obtained FDA approval for a 160 mg dose. "These high-milligram pills were probably one of the biggest reasons that OxyContin became such a popular street drug.... The euphoric effects and potential for abuse were comparable to heroin."<sup>8</sup> Prescriptions of Purdue's OxyContin for non-cancer related pain surged from approximately 670,000 in 1997 to 6.2 million by 2002, and the new 200% increased dose was specifically tailored to address the massive demand for the product and the legions of new addicts that it had created.<sup>9</sup> During this same time period Purdue Pharma launched and then

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<sup>8</sup> Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Pacific Standard, March 4, 2015, found at: <http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company> (last visited May 18, 2020).

<sup>9</sup> Van Zee A. *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-7.

quickly withdrew (upon demand by the FDA) a hydromorphone-based opiate “Palladone” after only six months on the market in 2005, because patients kept dying when they stopped breathing or else went into comas. The release of the deadly Palladone by Purdue was due to its concern about eroding market share when it lost a legal appeal to halt sales of a generic version of OxyContin.<sup>10</sup>

8. Notably, Purdue had an even earlier history of manufacturing opiates. Its product MS Contin (morphine based) had been profitable, but by the late 1980s, its patent was running out. OxyContin was developed, in the words of its VP for Clinical Research, to “cure the vulnerability of the ... generic threat [to MS Contin] and that is why it is so crucial that we devote our fullest efforts to a successful launch of OxyContin.”<sup>11</sup>

9. At all relevant times, Purdue and its co-conspirators manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of the prescription opioid drugs. The result of this behavior, as well as their failure in maintaining the mandated “closed system” for controlled substances, was to flood the market with highly addictive, dangerous opioids, whether through the primary prescription market (including to the birth mothers of the NAS children) and the illegally oversupplied secondary (or diversionary) market. At all times, Purdue and its co-conspirators have manufactured and distributed prescription opioids in the United States without fulfilling their legal duty to prevent

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<sup>10</sup> “Purdue Pulls Palladone Painkiller from Market,” July 15, 2005, found at [pharmatimes.com](http://pharmatimes.com) (last visited July 6, 2020).

<sup>11</sup> Harriet Ryan et al., *You Want a Description of Hell? OxyContin’s 12-Hour Problem*, Los Angeles Times, May 5, 2016, found at: <http://www.latimes.com/projects/oxycontin-part1/> (last visited: Oct. 17, 2018).

diversion and report suspicious orders. But for the dereliction of this legal duty, the robust secondary, diversionary market for opioids could not have existed.

## **II. PARTIES**

### **A. Plaintiff Legal Guardians and Putative Class Representatives**

10. Plaintiff Legal Guardian and Putative Class Representative Melissa Barnwell is a resident of California. She is the birth mother and legal guardian of Child C.G. and Child E.G., both of whom were diagnosed with NAS at or near birth. Melissa was medically prescribed opioids manufactured by Purdue, as well as opioids manufactured and distributed by one or more of Purdue's co-conspirators, prior to the births of Children C.G. and E.G.

11. Plaintiff Legal Guardian and Putative Class Representative Jacqueline Ramirez is a resident of California. She is the birth mother and legal guardian of Child R.R., who was diagnosed at or near birth with NAS. Jacqueline was medically prescribed opioids manufactured and/or distributed by one or more of Purdue's co-conspirators prior to and during her pregnancy with Child R.R.

12. Plaintiff and Putative Class Representative Ashley Poe is a resident of Ohio. She is the birth mother and legal guardian of Child P.P. who was diagnosed at or near birth with NAS. Ashley was medically prescribed opioids manufactured by Purdue, as well as opioids manufactured and/or distributed by Purdue's co-conspirators prior to her pregnancy with Child P.P.

13. Plaintiff and Putative Class Representative Anita Whigham is a resident of Oregon. She is the adoptive parent and legal guardian of Child J.C., who was diagnosed at or near birth with NAS. Upon information and belief, Child J.C.'s birth mother received medical prescriptions for opioids manufactured by Purdue, as well as opioids manufactured and distributed by Purdue's

co-conspirators, in the ten months prior to the birth of Child J.C. as well as at other times prior to the birth of Child J.C.

14. Plaintiff and Putative Class Representative Lyda Haag is a resident of Florida. She is the birth mother and legal guardian of Child L.V. who was diagnosed at or near birth with NAS. Lyda was medically prescribed opioids manufactured by Purdue, as well as opioids manufactured and distributed by Purdue's co-conspirators, in the ten months prior to the birth of Child L.V., as well as at other times prior to the birth of Child L.V.

15. The Legal Guardian Putative Classes are defined as:<sup>12</sup>

- a. Class 1: Legal Guardians<sup>13</sup> of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related "Neonatal Abstinence Syndrome" ("NAS")<sup>14</sup> at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured and/or distributed by Purdue.<sup>15</sup>
- b. Class 2: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS at or near birth and

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<sup>12</sup> The definitions of terms for Class 1 and Class 2 shall also apply to those same identical terms in the definitions for Classes 2-4 and are not repeated again for purposes of brevity.

<sup>13</sup> The term "Legal Guardian" is defined for purposes of this putative class action as "any natural person or entity who has the primary legal responsibility under their respective laws of their state for an infant or child's physical, mental, and emotional development." Expressly excluded from the class of "Legal Guardians" are any governmental entities. "Legal Guardians" include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

<sup>14</sup> The term "NAS" is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs' Motion for Class Certification.

<sup>15</sup> Defined in the "Parties" sections, *infra*, at § II. B. i.

whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured and/or distributed by one or more of Purdue's RICO Marketing Claim or RICO Supply Chain Claim co-conspirators.<sup>16</sup>

- c. Class 3: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received a prescription for opioids or opiates in the ten months prior to the birth and those opioids or opiates were manufactured and/or distributed by Purdue.
- d. Class 4: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related NAS at or near birth and whose birth mother received a prescription for opioids or opiates in the ten months prior to the birth and those opioids or opiates were manufactured and/or distributed by one or more of Purdue's RICO Marketing Claim or RICO Supply Chain Claim co-conspirators.
- e. Expressly excluded from the Classes are any infants or children who were treated with opioids neonatally, other than for pharmacological weaning. Also excluded from the class are Legal Guardianships where a governmental agency, such as a public children services agency, has affirmatively assumed the duties of "custodian" of the child.<sup>17</sup>

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<sup>16</sup> Defined in the "Parties" sections, *infra*, at § II. B. ii and iii.

<sup>17</sup> There are only two causes of NAS: (1) in utero exposure to opioids via the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed in utero and then treated with opioids pursuant to a

16. The Putative Class Representatives, like all Legal Guardians, have the absolute duty to protect the welfare of the NAS Children in their care. An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's unlimited and non-delegable duty of care owed to the child, as well as the absolute dominion of the Legal Guardian over the child.

17. The Putative Class Representatives, like all Legal Guardians, have been directly and foreseeably damaged and such damage will continue to occur in the future as they must continue to carry the substantial burdens and obligations of care for the NAS Children, as neonatal exposure to opioids necessarily results in medical needs that exist throughout the entire period of the NAS Children's adolescent development. These needs absolutely exist regardless of the dosage any one child received *in utero* or if they were pharmacologically weaned from these addictive substances. These needs relate primarily to the well-known adverse effects of opioids on behavioral and regulatory development in exposed children.

18. The Plaintiff Guardians and the Guardian Putative Class Members ongoing duty of care to the NAS Children requires the creation of an abatement trust that will fund ongoing medical monitoring and surveillance of the NAS Children, medical and developmental referral, provision of training and information for the Legal Guardians, a nationwide registry for NAS Children, and the convening and oversight of a Science Panel for purposes of epidemiological studies of the NAS Children at issue in this Complaint so that the implications of the NAS Children's' additional risk of disease and injury may be properly addressed during the administration of the Science Panel. To be clear, the Legal Guardians have direct and entirely foreseeable injuries-in-fact arising from their non-delegable duties of care owed to and dominion over NAS children who have both present

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weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

symptoms and a substantially increased risk of additional injury, disease, and disorder. Plaintiff Legal Guardians and the Putative Class Members have ongoing injuries resulting from Purdue and its co-conspirators' acts and these injuries will be abated by the relief requested. Indeed, without entry of the relief requested, Plaintiff Legal Guardians and the Putative Class Members cannot discharge their duties owed to the NAS Children. The Plaintiff Legal Guardians and Putative Class Members have suffered and continue to suffer these injuries.

**B. Defendant Debtor Purdue, the RICO Marketing Claim Co-Conspirators, and the RICO Supply Chain Claim Co-Conspirators**

**1. The Defendant Debtor Purdue**

19. The Defendant Debtor includes the following entities, Purdue Pharma L.P. ("PPL") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut. Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut. PPL, PPI, and PFC, and their DEA registrant subsidiaries and affiliates (collectively, "Purdue") are engaged in the manufacture, promotion, distribution, and sale of opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER throughout the United States. OxyContin is Purdue's best-selling opioid. The causal nexus of the acts and conspiracy alleged herein occurred predominantly in the State of New York, where, upon information and belief, the various members of the Sackler family (the founders, owners, and certain Officers and Directors of Purdue) lived and conducted business for and on behalf of Purdue, and where two of the Purdue companies were organized.

**2. The RICO Marketing Claim Co-Conspirators (Purdue, Cephalon, Janssen, Endo, and Mallinckrodt)**

20. Defendant Debtor Purdue acted jointly and in concert with the non-defendant, RICO Marketing Claim Co-Conspirators set out below. At all relevant times, the non-defendant RICO Marketing Claim Co-Conspirators manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to accurately represent the benefits and risks associated with the use of prescription opioid drugs. Their acts flooded the United States with highly addictive, dangerous opioids, whether through the primary prescription market (including to United States women of child-bearing age and pregnant women) and the secondary market. At all times, Purdue and its co-conspirators have manufactured (including supplying of processed active pharmaceutical ingredients (APIs) to each other) and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders. But for the dereliction of this legal duty, the robust secondary market for opioids could not have existed in the United States.

**a. Cephalon**

21. Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”), an Israeli corporation (collectively “Teva”).

22. Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

23. Teva USA and Cephalon, Inc. and their DEA registrant subsidiaries and affiliates (collectively, “Cephalon”) work together to manufacture, promote, distribute, and sell both brand name and generic versions of Schedule II opioids including Fentanyl.

24. From 2000 forward, Cephalon has made thousands of improper payments to physicians nationwide. Many of these doctors were not oncologists and did not treat cancer pain. The payments were made ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids, thereby corrupting the appropriate standard of care.

**b. Janssen**

25. Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

26. Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey and is a wholly owned subsidiary of J&J. J&J corresponds with the FDA regarding Janssen's products. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

27. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware, and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

28. Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("OMP"), n/k/a Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

29. Janssen Pharmaceutica, Inc. ("Janssen Pharmaceutica"), n/k/a Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

30. J&J, Janssen Pharmaceuticals, OMP, and Janssen Pharmaceutica and their DEA registrant subsidiaries and affiliates (collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally. Fentanyl is among the Schedule II drugs<sup>18</sup> that Janssen manufactures or manufactured.

31. Janssen made thousands of payments to physicians nationwide, ostensibly for activities that include participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

32. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization’s mission, values and principles. Janssen’s employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J’s and Janssen’s websites confirm J&J’s control of the development and marketing of opioids by Janssen. Janssen’s website “Ethical Code for the Conduct of Research and Development,” names only J&J and does not mention Janssen anywhere within the document. The “Ethical Code for the Conduct of Research and Development” posted on the Janssen website is J&J’s company-wide Ethical Code, which it requires all of its subsidiaries to follow.<sup>19</sup>

33. The “Every Day Health Care Compliance Code of Conduct” posted on Janssen’s website is another J&J company-wide document that describes Janssen as one of the “Pharmaceutical Companies of Johnson & Johnson” and as one of the “Johnson & Johnson

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<sup>18</sup> Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

<sup>19</sup> <https://www.jnj.com/about-jnj/policies-and-positions/ethical-code-for-the-conduct-of-research-and-development>

Pharmaceutical Affiliates.” It governs how “[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates,” including those of Janssen, “market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates’ products.” All Janssen officers, directors, employees and sales associates must certify that they have “read, understood and will abide by” the code. The code governs all of the forms of marketing at issue in this case.

34. J&J also made payments to thousands of physicians nationwide, ostensibly for activities including participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids, thereby corrupting the appropriate standard of care.

35. Information from the U.S. Department of Justice’s Office of the Inspector General shows that J&J made payments to prescribers but does not indicate which drug was being promoted when J&J made these payments. At least one prescriber who previously served on Janssen’s speakers’ bureau received payment for speaking fees, meals, and travel from J&J. Upon information and belief, J&J would have similarly made payments to other participants in Janssen’s speakers’ bureau.

**c. Endo**

36. Endo Health Solutions Inc. (“EHS”) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

37. Endo Pharmaceuticals, Inc. (“EPI”) is a wholly owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

38. Par Pharmaceutical, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. Par

Pharmaceutical Companies, Inc. is a Delaware corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are collectively referred to as “Par Pharmaceutical.” Par Pharmaceutical was acquired by Endo International plc. in September 2015 and is an operating company of Endo International plc.

39. EHS, EPI, and Par Pharmaceutical and their DEA registrant subsidiaries and affiliates (collectively, “Endo”) manufacture opioids sold nationally, and in the State of New York.

40. Endo made thousands of payments to physicians nationwide, including in the State of New York, ostensibly for activities that include participating on speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids, thereby corrupting the appropriate standard of care.

41. Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012, accounting for over 10% of Endo’s total revenue; Opana ER yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiaries, Par Pharmaceutical and Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

42. The Food and Drug Administration requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on risk of abuse.<sup>20</sup>

**d. Mallinckrodt**

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<sup>20</sup> Press Release, U.S. Food & Drug Admin., FDA Requests Removal of Opana ER for Risks Related to Abuse (accessed June 8, 2017).

43. Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June of that year. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri. Mallinckrodt LLC is a Delaware corporation with its headquarters in Hazelwood, Missouri.

44. SpecGx LLC is a Delaware limited liability company with its headquarters in Clayton, Missouri, and is a wholly owned subsidiary of Mallinckrodt plc. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together “Mallinckrodt”) manufacture, market, sell, and distribute pharmaceutical drugs throughout the United States. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States, based on prescriptions.

45. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014 and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

46. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received

approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health data for the same period, that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.<sup>21</sup>

47. Mallinckrodt operates a vertically integrated business in the United States: importing raw opioid materials, manufacturing generic opioid products, primarily at its facility in Hobart, New York, and marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

48. Among the drugs that Mallinckrodt manufactures or has manufactured are oxycodone hydrochloride and methadone hydrochloride.

49. Mallinckrodt made thousands of payments to physicians nationwide, ostensibly for activities that include participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids, thereby corrupting the appropriate standard of care.

50. Purdue, Cephalon, Janssen, Endo, and Mallinckrodt are collectively referred to as the "RICO Marketing Claim Co-Conspirators"; however, only the Debtor Purdue is a defendant in this proceeding.<sup>22</sup>

**3. The RICO Supply Chain Claim Co-Conspirators (Purdue, Cephalon, Endo, Mallinckrodt, McKesson, Cardinal, AmerisourceBergen, and Actavis)**

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<sup>21</sup> Mallinckrodt plc, Annual Report (Form 10-K). 5 (N5 (Nov. 29, 2016), <https://www.sec.gov/Archives/edgar/data/1567892/000156789216000098/0001567892-16-000098-index.htm>).

<sup>22</sup> Together, Cephalon, Janssen and Endo are also sometimes referred to as "RICO Marketing Manufacturers."

51. At all times Defendant Debtor Purdue acted jointly and in concert with the RICO Supply Chain Co-Conspirators, comprised of Cephalon, Endo, and Mallinckrodt (which are also RICO Marketing Claim Co-Conspirators), as well as McKesson, Cardinal, AmerisourceBergen, and Actavis. Collectively, they are referred to as the “RICO Supply Chain Claim Co-Conspirators.”

52. At all relevant times, the RICO Supply Chain Claim Co-Conspirators have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The RICO Supply Chain Claim Co-Conspirators failed to comply with federal and/or state law. The RICO Supply Chain Claim Co-Conspirators are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiffs allege the unlawful conduct by the RICO Supply Chain Claim Co-Conspirators is a substantial, contributing cause for the volume of prescription opioids plaguing this country.

**a. Purdue, Cephalon, Endo, and Mallinckrodt**

53. For the purpose of brevity, Plaintiffs incorporate by reference the factual allegations previously made regarding these entities.

**b. Cardinal Health, Inc.**

54. Cardinal Health, Inc. (“Cardinal”) describes itself as a “global, integrated health care services and products company” and is the fifteenth largest company by revenue in the U.S., with annual revenue of \$121 billion in 2016. Through its various DEA registered subsidiaries and affiliated entities, Cardinal distributes pharmaceutical drugs, including opioids, throughout the country. Cardinal is an Ohio corporation and is headquartered in Dublin, Ohio. Cardinal, including its subsidiaries and affiliated entities, has been licensed as a wholesale distributor of dangerous

drugs throughout the United States. Based on Cardinal's own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

**c. AmerisourceBergen Drug Corporation**

55. AmerisourceBergen Drug Corporation ("AmerisourceBergen"), through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. AmerisourceBergen is the eleventh largest company by revenue in the United States, with annual revenue of \$147 billion in 2016. AmerisourceBergen's principal place of business is located in Chesterbrook, Pennsylvania, and it is incorporated in Delaware. AmerisourceBergen has been licensed as a wholesale distributor of drugs since 1988.

**d. McKesson Corporation**

56. McKesson Corporation ("McKesson") is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with annual revenue of \$191 billion in 2016. McKesson, through its various DEA registered subsidiaries and affiliated entities, is a wholesaler of pharmaceutical drugs that distributes opioids throughout the country. McKesson is incorporated in Delaware, with its principal place of business in San Francisco, California.

57. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice ("DOJ") for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these "staged suspensions" as "among the most severe sanctions ever agreed to by a [Drug Enforcement Administration] registered distributor."

**e. Actavis**

58. Allergan plc (f/k/a Actavis plc f/k/a Allergan, Inc.) is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland, and its administrative headquarters and all executive officers located in Madison, New Jersey. In October 2012, the Actavis Group was acquired by Watson Pharmaceuticals, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then to Actavis plc in October 2013. In October 2013, Actavis plc (n/k/a Allergan plc) acquired Warner Chilcott plc pursuant to a transaction agreement dated May 19, 2013. Actavis plc (n/k/a Allergan plc) was established to facilitate the business combination between Actavis, Inc. (n/k/a Allergan Finance, LLC) and Warner Chilcott plc. Following the consummation of the October 1, 2013 acquisition, Actavis, Inc. (n/k/a Allergan Finance, LLC Inc.) and Warner Chilcott plc became wholly owned subsidiaries of Actavis plc (n/k/a Allergan plc). Pursuant to the transaction, each of Actavis, Inc.'s common shares were converted into one Actavis plc share. Further, Actavis plc (n/k/a Allergan plc) was the "successor issuer" to Actavis, Inc. and Warner Chilcott. Actavis plc acquired Allergan, Inc. in March 2015, and the combined company thereafter changed its name to Allergan plc in January 2013.

59. Allergan Finance, LLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.) is a limited liability company incorporated in Nevada and headquartered in Madison, New Jersey. Allergan Finance, LLC is a wholly owned subsidiary of Allergan plc. In 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. Since 2008, Kadian's label has identified the following entities as the manufacturer or distributor of Kadian: Actavis Elizabeth LLC, Actavis Kadian LLC, Actavis Pharma, Inc., and Allergan USA, Inc. Currently, Allergan USA, Inc. is contracted with UPS SCS, Inc. to distribute Kadian on its behalf.

60. Allergan Sales, LLC is incorporated in Delaware and headquartered in Irvine, California. Allergan Sales, LLC is the current New Drug Application (“NDA”) holder for Kadian, and in 2016, Allergan Sales, LLC held the Abbreviated New Drug Applications (“ANDAs”) for Norco.<sup>23</sup> Allergan Sales, LLC is a wholly owned subsidiary of Allergan plc.

61. Allergan USA, Inc. is incorporated in Delaware and headquartered in Madison, New Jersey. Allergan USA, Inc. is currently responsible for Norco and Kadian sales. Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc.

62. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California. Watson Laboratories, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic business to Teva. Prior to the sale, Watson Laboratories, Inc. was a direct subsidiary of Actavis, Inc., (n/ka/ Allergan Finance, LLC). Between 2000 and 2015, Watson Laboratories, Inc. held the ANDAs for Norco and was the manufacturer of the drug. Watson Laboratories, Inc. was also the ANDA holder of various generic opioids.

63. Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. Warner Chilcott Company LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc’s 2016 sale of its generic businesses to Teva.

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<sup>23</sup> The Norco ANDAs are currently held by Allergan Pharmaceuticals International Limited, which is incorporated in Ireland.

64. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the New York Secretary of State as a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) was previously responsible for sales of Kadian and Norco. Actavis Pharma, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

65. Actavis South Atlantic LLC is a Delaware limited liability company with its principal place of business in Sunrise, Florida. Actavis South Atlantic LLC was listed as the ANDA holder for oxymorphone and fentanyl transdermal. Actavis South Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

66. Actavis Elizabeth LLC is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. From December 19, 2005, until it purchased the medication in December 2008, Actavis Elizabeth LLC served as the contract manufacturer of Kadian for Alpharma. Actavis Elizabeth LLC held the NDA for Kadian from 2008 to 2013. Actavis Elizabeth LLC was also the holder of ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen; homatropine methylbromide/hydrocodone bitartrate; morphine sulfate capsule; morphine sulfate tablet; oxycodone/hydrochloride tablet; oxycodone/ibuprofen; and oxymorphone tablet. Actavis Elizabeth LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

67. Actavis Mid Atlantic LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Mid Atlantic LLC has held the ANDA for homatropine methylbromide/hydrocodone bitartrate. Actavis Mid Atlantic LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

68. Actavis Totowa LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis Totowa LLC has held the ANDAs for the following Schedule II opioid products: oxycodone/acetaminophen, homatropine methylbromide; oxycodone/hydrochloride.

69. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, and Actavis Totowa LLC were all direct subsidiaries of Actavis LLC, which was an indirect subsidiary of Watson Laboratories, Inc. Watson Laboratories, Inc., in turn, was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Actavis LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

70. Actavis Kadian LLC is a Delaware limited liability company with its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has been identified on Kadian's label as a manufacturer or distributor of Kadian. Actavis Kadian LLC was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva.

71. Actavis Laboratories UT, Inc. (f/k/a Watson Laboratories, Inc.-Salt Lake City) is a Delaware limited liability company with its principal place of business in Salt Lake City, Utah. Actavis Laboratories UT, Inc. was the Kadian NDA holder from 2013 to 2016 and was listed as the NDA holder for morphine sulfate capsule. Actavis Laboratories UT, Inc. was sold to Teva Pharmaceutical Industries Limited as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories UT, Inc. was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC).

72. Actavis Laboratories FL, Inc. (f/k/a Watson Laboratories, Inc.-Florida) is a Florida limited liability company with its principal place of business in Davie, Florida. Actavis

Laboratories FL, Inc. was a Norco ANDA holder in 2015 and was the ANDA holder of the following Schedule II opioid products: hydrocodone/acetaminophen; hydrocodone/ibuprofen; oxycodone/ aspirin; and hydromorphone tablet. Actavis Laboratories FL, Inc. was sold to Teva Pharmaceutical Industries Ltd. as part of Allergan plc's 2016 sale of its generic businesses to Teva. Prior to the sale, Actavis Laboratories FL, Inc. was a direct subsidiary of Andrx Corporation, which was a direct subsidiary of Actavis, Inc. (n/k/a Allergan Finance, LLC). Andrx Corporation was transferred to Teva as part of the 2016 sale.

73. Each of these entities is currently or was previously owned by Allergan plc, which uses them to market and sell its drugs in the United States. Collectively, these entities, and their U.S. Drug Enforcement Administration's ("DEA") registrant subsidiaries and affiliates which manufacture, promote, distribute, and sell prescription opioids, are referred to as "Actavis."

74. Actavis manufactures or has manufactured Schedule II drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States.

75. The "RICO Supply Chain Claim co-conspirators" include the previously-named RICO Marketing Claim co-conspirators, as well as McKesson, Cardinal, AmerisourceBergen, and Actavis.

### **III. JURISDICTION AND VENUE**

76. This adversary proceeding is authorized by Federal Rule of Bankruptcy Procedure 7001(7) because this action is a proceeding to obtain equitable relief.

77. Pursuant to Federal Rule of Bankruptcy Procedure Rule 7008, this adversary proceeding relates to the Chapter 11 case *In re Purdue Pharma L.P., et al.*, Case No. 19-23649 (RDD).

78. This Court has jurisdiction to consider this adversary proceeding and subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 157 and 1334.

79. This Court has personal jurisdiction over Purdue and its co-conspirators pursuant to Federal Rule of Bankruptcy Procedure 7004(f).

80. Venue is proper in this district pursuant to 28 U.S.C. § 1409(a) because this action is a proceeding arising in or related to a case under title 11 of the United States Code pending in this district.

81. This Court has personal jurisdiction over Purdue pursuant to Federal Rule of Bankruptcy Procedure 7004(f).

82. This adversary proceeding is authorized by Federal Rule of Bankruptcy Procedure 7001(7) because this action is a proceeding to obtain equitable relief.

83. This Court is further vested with jurisdiction by virtue of the Bankruptcy Code 7023 which adopts Federal Rule of Civil Procedure 23 and expressly permits class actions in adversary proceedings (“Rule 23 Fed. R. Civ. P. applies in adversary proceedings.”). The proposed class exceeds 100 persons. Further, the amount in controversy exceeds \$5,000,000.00, as the aggregated value of the benefit to the Class will exceed \$5,000,000.<sup>24</sup>

#### **IV. PROCEDURAL HISTORY**

84. For almost three years, various Legal Guardians have sought classwide relief to benefit the NAS Children in their care. Cases were filed in state and federal courts, with most being pulled into the *In re National Prescription Opiate Litigation*, MDL No. 2804, in the Eastern District of Ohio, Hon. Judge Dan Aaron Polster presiding.

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<sup>24</sup> Class Action Fairness Act, 28 U.S.C. § 1332(d).

85. Prior to Purdue's filing for bankruptcy, the MDL Court denied, in principal part, motions to dismiss brought by Purdue and its same co-conspirators on same factual basis alleged herein as well as the near-identical RICO Marketing Claims and RICO Supply Chain Claims asserted in this action in a bellwether case (the "Summit Action") brought by a municipality (Summit County, Ohio).<sup>25</sup>

86. From the outset of the MDL proceeding, certain NAS Guardians (whose claims were in no way being advanced by the PEC of the MDL whether through discovery or inclusion in pleadings) sought the ability to proceed on a separate track within the MDL to advance the monitoring and surveillance abatement. It was not until after the filing of the Bankruptcy petition by Purdue in this Court, that Judge Polster finally allowed the NAS Guardians to amend their class complaints in the MDL (with an order for a Consolidated Complaint on behalf of all representatives and the classes and subclasses they sought to represent) and proceed with class discovery and a class certification briefing schedule.<sup>26</sup> See Amended Class Action Complaints, *In re Nat'l Prescription Opiate Litig.*, No. MDL 2804, Docket Entries 2745 and 2747, dated 10/08/2019, and Motion for Class Certification, *id.* at Docket Entry 3066, dated 01/07/20.

87. After the filing of the NAS Guardians' Motion for Class Certification in early January, 2020, and expert and class representative discovery (exchange of expert reports, written discovery of the putative class representatives, depositions of all but one of the putative class representatives, depositions of all of the Plaintiffs' experts, and depositions of approximately half of Purdue and its co-conspirators' experts) commenced. The necessarily in-person process which was spread across the United States ground to a halt in early March, 2020, as the COVID-19

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<sup>25</sup> *In re Nat'l Prescription Opiate Litig.*, No. MDL 2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018).

<sup>26</sup> *In re Nat'l Prescription Opiate Litig.*, No. MDL 2804, Docket Entry 2691 "Amended Joint Proposed Briefing Schedule Order" dated 09/30/2019 and Granted 10/01/2019 [non-document].

Pandemic made travel impossible for most of the attorneys and remaining deponents, made in-person depositions highly risky, and caused extreme burdens on medical and epidemiological experts who had new and immense COVID-19 practice obligations. Thus, while a resolution of the NAS Guardian class motion in the MDL would not have been dispositive of the issues now before this Court, it might have offered some guidance. Regardless, that has not occurred.

88. The filing of this Class Action Complaint as part of the Motion to Extend Application of Fed. R. Civ. P. 23 to Class Proof of Claims is now timely. Notably, for the past three and a half months attorneys for the Putative Class Representatives named herein have been involved in intense negotiations within the court-ordered mediation process advocating for the abatement relief requested on behalf of the putative class.

## **V. FACTS**

### **A. Introduction**

89. Purdue single-handedly spawned the Opioid epidemic in America and then acted in concert with its co-conspirators who eagerly jumped into the burgeoning market. Purdue and its co-conspirators extracted billions and billions of dollars in profit from these efforts as they collectively doomed NAS Children to lives of significant mental and developmental challenges.<sup>27</sup> Purdue's and its co-conspirators' marketing efforts (including misrepresentations, omissions, and improper payments to medical professionals) so significantly altered the standard of care for the treatment of both minor and severe injuries, as well as chronic disorders, that a tidal wave of highly-addictive controlled substances was unleashed on the American public, including pregnant

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<sup>27</sup> The Purdue Debtor Defendants are set out, *supra*, at § II. B. i. and are referred to throughout this Complaint interchangeably as "Purdue," "Debtor," or "Purdue Pharma." For the purposes of this Complaint, all allegations set forth herein related to or pertaining to Purdue's co-conspirators listed, *supra*, in § II. B. ii. and iii., apply equally to Purdue.

women and women of childbearing years, who succumbed to dependency and addiction. And the bad acts of Purdue and its co-conspirators did not stop with their marketing scheme. They also acted jointly and in conspiracy to destroy the “closed system” of distribution of controlled substances within the United States so that they could create and profit handsomely from the secondary diversionary market. Most importantly, however, Purdue and its co-conspirators perpetrated these schemes with full knowledge of the extreme potential for harm from in utero opioid exposure.

## **B. Opioids and NAS**

90. Opioids are a class of drugs derived in whole or part from the poppy plant. These powerful euphoria-producing and pain-reducing medications include oxycodone, hydrocodone, and morphine. While the drugs have benefits, those must be balanced against the known risk of serious harm, including addiction, overdose, death, and injury to the fetus. Women who use opioids during their pregnancy are at exceptionally high risk for giving birth to a baby who suffers from NAS. Plaintiffs and the putative class members are Legal Guardians of NAS Children who were all diagnosed at birth with opioid-related NAS. By definition, there are no “exposure-only” or “asymptomatic” NAS Children for whom the Legal Guardians owe a duty of care.

91. The number of infants born suffering from this insidious condition is staggering. The incidence of NAS in the United States grew five-fold between 2000 and 2012.<sup>28</sup> Specifically, cases of NAS increased nationally from a rate of 1.2 per 1000 hospital births per year in 2000 to

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<sup>28</sup> Patrick SW, et al, *Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009-2012*, J Perinatol. 2015 Aug; 35(8):650-5

5.8 per 1000, with a total of 21,732 infants diagnosed by 2012.<sup>29</sup> The best estimates are that a child with NAS is born every 25 minutes.<sup>30</sup>

92. NAS-diagnosed children “are at increased risk for neuropsychological function.”<sup>31</sup> The challenges presented to them and their caregivers at birth are summarized as: “Do they catch up, remain at a disadvantage, or do they proceed to function even more poorly than their peers over time?”<sup>32</sup> Unfortunately, the new research borne about as a result of the Opioid Epidemic reveals that all NAS-diagnosed infants and children “will have lower mental abilities and more signs of attention deficit.”<sup>33</sup>

93. Specifically, children diagnosed with NAS exhibit:

- a. by age 1: diminished performance on the Psychomotor Development Index,<sup>34</sup> growth retardation,<sup>35</sup> poor fine motor skills,<sup>36</sup> short attention span,<sup>37</sup> intellectual performance<sup>38</sup>;

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<sup>29</sup> *Id.*; Patrick SW, et al, *Neonatal abstinence syndrome and associated health care expenditures: United States, 2000-2009*, JAMA. 2012 May 9; 307(18):1934-40.

<sup>30</sup> *Id.*

<sup>31</sup> Nygaard E., *Longitudinal cognitive development of children born to mothers with opioid and polysubstance use*, *Pediatr Res*. 2015 Sep; 78(3):330-5.

<sup>32</sup> *id*

<sup>33</sup> *Id.* And, this is regardless of whether the child is removed from its birth mother or is in the care of a different Legal Guardian. *Id.*

<sup>34</sup> Strauss ME, et al, *Behavioral concomitants of prenatal addiction to narcotics*, J. *Pediatr*. 1976 Nov; 89(5):842-6; Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications*, J. *Pediatr*. 1981 May; 98(5):716-22.

<sup>35</sup> Strauss ME, et al, *Behavioral concomitants of prenatal addiction to narcotics*, J. *Pediatr*. 1976 Nov; 89(5):842-6.

<sup>36</sup> Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications*, J. *Pediatr*. 1981 May; 98(5):716-22, and Bunikowski R, et al, *Neurodevelopmental outcome after prenatal exposure to opiates*, *Eur J Pediatr*. 1998 Sep; 157(9):724-30.

<sup>37</sup> Wilson GS, et al, *Follow-up of methadone-treated women and their infants: Health, development, and social implications*, J. *Pediatr*. 1981 May; 98(5):716-22.

<sup>38</sup> Bunikowski R, et al, *Neurodevelopmental outcome after prenatal exposure to opiates*, *Eur J Pediatr*. 1998 Sep; 157(9):724-30.

- b. between ages 2-3: significantly lower cognitive abilities, including lower motor development, lower IQ, and poor language development;
- c. between ages 3-6: significant detrimental impact on self-regulation, including aggressiveness, hyperactivity, lack of concentration, lack of social inhibition,<sup>39</sup> lower IQs (8-15 point difference), poor language development, and behavioral and school problems; and
- d. 8.5 years and older: significantly greater difference in cognitive scores than at previous ages, especially in girls.<sup>40</sup>

94. The Legal Guardians must care for NAS Children who suffer from and face an increased risk of lifelong mental illness, mental impairment, loss of mental capacity, and addiction. The Legal Guardian's must discharge their duties to protect the NAS Children's welfare, including their entire health, their use of their bodies and minds, and their developmental outcomes, including their ability to avoid opiate addiction, learn, work normally, enjoy relationships with others, and function as a valuable citizen, child, parent, income-earner, and person enjoying life.

95. The NAS Children sustained an exposure to opioids greater than that expected by members of the general population. Indeed, they were all born addicted.

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<sup>39</sup> Oloffson M, et al., *Investigation of 89 children born by drug-dependent mothers. II. Follow-up 1-10 years after birth*, Acta Paediatr Scand. 1983; 72:407-10; The researchers in this study came to the heartbreaking conclusion that "[T]here is an urgent need for health personnel to reexamine their roles in helping these children, who will otherwise develop into a new generation of social losers." *Id.*

<sup>40</sup> Nygaard E, *Longitudinal cognitive development of children born to mothers with opioid and polysubstance use*, Pediatric Res. 2015 Sep; 78(3):330-5.

96. NAS is a generalized multi-system disorder that produces a constellation of symptoms in neonates and results from abrupt discontinuation of opioids consumed by the mother during pregnancy at the infant's birth.

97. Opioids represent a single class of exposures since they all cause their effects at the same receptors which are those that mediate the effects of endogenous opiates

98. Opioids represent a single class of chemical substances since their molecular structures are very essentially the same.

99. Opioids have typical pharmacological effects which are common to the group: effects on the brain, nervous system and gastrointestinal system. The opioid compounds all act at the same biological receptors and mimic natural peptides which have powerful and wide-ranging activity in living systems. Thus, they can be considered a class of chemical drugs both in terms of their pharmacological dosage activity relationships and also their overall chemical structure. They produce common effects, bind to common receptors, and also have similar chemical structures. They all produce addiction and dependence and cause withdrawal symptoms on removal. Their activity as modulators of neurological signaling make them especially dangerous in adults due to rebound effects but are also known to have significant effects on fetal development since they alter the cellular signaling environment.

100. The effect of all opioids is produced through a single common pathway – the opioid receptor. The opioid receptor system is ancient and highly conserved, being present by the time that jawed vertebrates first appeared at least 450 million years ago. Clearly, differences between opioid products and potency exist but their mode of action via the opioid receptor system remains identical.

101. Opioids cross the blood-brain barrier as well as the placenta.

102. Fetal development relies on the balanced control of cell proliferation and cell death through apoptosis (otherwise termed "programmed cell death").

103. It is scientifically demonstrated that exposure to opiates will increase the rate of apoptotic cell death in developing biological systems. This represents a common mode of action which leads to the large plethora of adverse conditions associated with fetal opioid exposure, including – sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function.

104. It is scientifically demonstrated that exposure to opiates will interfere with the normal process of apoptosis by increasing the rate of apoptotic cell death in developing biological systems, specifically fetal brains. Interference of normal apoptosis represents a common mode of action leading to a plethora of adverse conditions in the fetus, including sub-optimal brain maturation, a form of functional teratogenesis associated with reduced cognitive function.

105. All NAS Children made the subject of the class were objectively diagnosed at or near birth with NAS, so that there is no question of whether the dose was sufficient to cause NAS, regardless of whether there was an interruption during.

106. The ongoing and robust medical monitoring and treatment of opioid-related NAS-diagnosed children is medically necessary. And, further, this is a rapidly transforming field, as multiple members of child care, psychological, and medical personnel are coming together to determine the best protocols for improving the outcomes after a diagnosis. *Hence, the absolute necessity that this Court convene a Science Panel.* For example, a recent (albeit extremely limited in size and geography), pilot program operated by the State of Kentucky's State Health Service Program offers a view of necessary treatment components after hospital discharge: (1) education of caregivers for techniques to relieve infant distress, including infant massage, calming

techniques, and other coping skills; (2) education of caregivers about NAS and the associated symptoms; (3) frequent follow-up of the infant for growth and weight gain; (4) monthly development evaluations during infancy and toddler years to determine whether additional interventions and treatment are necessary.<sup>41</sup>

107. Researchers at Ohio's Case Western Reserve University School of Medicine recommend similar protocols, noting: "Intervention services for this population need to extend beyond infancy and the toddler years, since problems in cognitive, language, and behavioral functioning may persist throughout childhood."<sup>42</sup> In addition to the caregiver (i.e., Legal Guardian) training, they recommend the following: specific individual therapy for speech and language, occupational, and behavioral; early intervention/enrichment; and ongoing cognitive and behavioral assessment.<sup>43</sup> Regarding the time-span of necessary assessment and intervention, the researchers write: "Developmental and assessment and intervention should continue during the preschool and school years, when children may benefit from enriched educational programs and screening for special education services. Problems can compound when cognitive demands increase during the early school years. Other critical transition periods occur in the first, fourth, and sixth or seventh grades, when subtle learning of behavior problems may become more evident and lead to functional impairment."<sup>44</sup> Of equal concern is that these deficits may themselves lead to the creation of another generation of addicts. Dr. Barry Lester writes in the *Journal of Addiction Disorders*: "Prenatal drug exposure ... may lead to lasting behavioral dysregulation that increases

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<sup>41</sup> Kentucky Cabinet for Health and Family Services, Nutrition Branch, Newsletter (Fall/Winter 2016 supp.), <http://chfs.ky.gov/NR/ronlyres/FFF6F900-9982-412F-BEA5-E82542E6DF0F/0/NutritionBranchNewsletter24Supplement.pdf> (page no longer hosted on site).

<sup>42</sup> Minnes S., et al, *Prenatal Tobacco, Marijuana, Stimulant, and Opiate Exposure: Outcomes and Practice Implications*, *Addict Sci Clin Pract.* 2011 Jul; 6(1):57-70.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

vulnerability to substance use, resulting in early onset substance use in adolescents.”<sup>45</sup> *Due to the substantially increased risk of disease and addiction, failure to provide the Legal Guardians with the requested abatement of medical monitoring and surveillance will necessarily lead to “In re National Prescription Opiate Litigation 2.0” as the NAS Children become the next generation of American opioid addicts.*

**C. Extensive Pharmaceutical Industry Knowledge Regarding the Effects of In Utero Opioids Exposure (Including NAS)**

108. Long before Purdue and its co-conspirators began manufacturing, marketing, and distributing prescription opioids, doctors and scientists around the world recognized the relationship between opiates, birth defects and brain damage. In the 1960s and 1970s, researchers conclusively linked fetal opioid exposure to teratogenic, mutagenic, genotoxic, and clastogenic defects. In other words, at the time of Purdue’s disclosures to the FDA in the early 1990s, it was established science that opioid use in an expectant mother could cause brain damage and birth defects, not the simple and short-term “fussiness” that Purdue sought to promote.

109. In 1975, findings reported in the International Journal of Epidemiology showed clear association between opioid use and the incidence of cleft palates in newborns.

110. In 1981, Obstetrics Gynecology published a study linking pre-natal opioid exposure to congenital malformations. That research was consistent with an article that appeared in the Journal of the American Medical Association that same year addressing opioid use and congenital malformations in the first trimester.

111. In 1982, Pediatrics reported linkage to birth defects in a study of poly-drug and methadone-addicted newborns.

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<sup>45</sup> Lester B., et al, *Children of Addicted Women*, J Addict. Dis. 2010; 29(2): 259-276. Doi.10.1080/10550881003684921.

112. In 1985 and 1986, the New England Journal of Medicine published articles by separate authors relating opioid exposure to heart defects in newborns.

113. In 1990, an article appearing in the American Journal of Obstetric Gynecology addressed the issue of perinatal impact of opiate use.

114. In 1991, the European Journal of Epidemiology reported links to fetal opioid exposure and congenital cardiac anomalies which built upon the earlier research published by the New England Journal of Medicine.

115. Yet, Purdue and its co-conspirators spearheaded a global conspiracy to deny this industry knowledge and to sow confusion about the existing medical literature. Again, just like lying opioids' addictive nature was profitable, lying about the dangers of *in utero* exposure made Purdue and its co-conspirators billions of dollars.

116. It is undisputed that Purdue never took any efforts to warn of the potentially disastrous long-term effects of *in utero* opioid exposure on children. Further, Purdue refused to conduct or fund research on the matter. Indeed, Purdue's Vice President of Clinical Research, Dr. Robert Kaiko, testified that Purdue never even considered that it should research (or else fund independent, third-party researchers) regarding the long-term effects of *in utero* opioid exposure, despite the fact that warning bells about these effects were being issued by the medical and scientific communities for over a decade and Purdue had actual knowledge that hundreds of thousands of pregnant women and women of child-bearing age were taking its highly addictive products.<sup>46</sup> Purdue actively and knowingly lied about Oxycodone's long-term danger to the fetus which made it easy to sell pregnant women billions of pain pills designed for terminal cancer patients.

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<sup>46</sup> Deposition of Robert Kaiko, PhD, Nov 28, 2018, *In re National Opiate Litigation*, MDL No. 2804, pp. 261-265.

**D. Controlled Substances and the “Closed System” of Manufacturing and Distribution**

117. Prescription opioids, which are the sole cause of *in utero* NAS, have an extremely high potential for addiction and injury and are categorized by the United States government as “Schedule II Controlled Substances.”<sup>47</sup> The definition of such is described by the United States Department of Justice’s Drug Enforcement Agency (DEA), Diversion Control Division on its public website:

ScheduleII/IIN Controlled Substances (2/2N)

Substances in this schedule have a high potential for abuse with may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.<sup>48</sup>

118. Because of their known high potential for injury and addiction, these prescription drugs may only be manufactured and distributed within a “closed” system in which gatekeepers (Purdue and its RICO Marketing Claim and RICO Supply Chain Claim co-conspirators) are charged with the duty to prevent diversion of drugs out of the legitimate channels and into the illicit market. The Debtor Purdue and its co-conspirators’ complete and abject failure to maintain the closed system was the direct and proximate cause of the harm described in this Complaint.

119. The Debtor Purdue and its RICO Marketing Claim co-conspirators were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of registration is the “maintenance of *effective controls against diversion* of particular controlled substances and any

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<sup>47</sup> *See* Controlled Substances Act, 21 U.S.C. § 812, as supplemented by Title 21, C.F.R. § 1308.

<sup>48</sup> *See* <https://www.deadiversion.usdoj.gov/schedules/> (last visited Oct. 17, 2018).

controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes. 21 U.S.C. § 823(a)(1) (emphasis added). Additionally, as “registrants” under Section 823, Debtor Purdue and its RICO Marketing Claim co-conspirators were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act” (21 U.S.C. 823 or 958)).

120. Similarly, and of equal importance, Purdue and its RICO Supply Chain Co-Conspirators was also required to register with the DEA pursuant to the Federal Controlled Substance Act. *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100. Each is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.” 21 U.S.C. § 823(b)(1). As with manufacturers, federal regulations impose a *non-delegable duty* upon wholesale drug distributors to “design and operate a system to

disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21 C.F.R. § 1301.74(b).<sup>49</sup>

121. In addition to reporting all suspicious orders, Purdue and its co-conspirators must also *affirmatively stop shipment on any order which is flagged as suspicious* and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.<sup>50</sup> Regardless, all flagged orders must be reported. *Id.*

122. Per the DEA in a letter to Purdue and its co-conspirators in 2006, wholesale distributors are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the

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<sup>49</sup> These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b).

<sup>50</sup> See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf’t Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

health and general welfare of the American people.”<sup>51</sup> Additionally, “*even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.*”<sup>52,53</sup>

**E. In Intentional and Wanton Disregard of Their Duties under the “Closed System,” Purdue and its RICO Marketing Claim Co-Conspirators Create Two New Markets for Prescription Opioids (and the RICO Supply Chain Co-Conspirators Aid Them Every Step of the Way)**

123. Purdue and its co-conspirators’ profits were theoretically limited by the amount of medically necessary opioids that could be sold through controlled channels. *The stark reality Purdue and its co-conspirators faced was this: they could only sell so many prescription opioids to dying cancer patients.* “The logic was simple: While the number of cancer patients was not

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<sup>51</sup> Letter from Joseph T. Rannazzisi, Dep. Asst. Adm’r, Office of Diversion Control, Drug Enforcement Admin, U.S. Dept. of Justice to Cardinal Health (Sept. 27, 2006). (“This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Agency (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.”).

<sup>52</sup> *Id.*

<sup>53</sup> The DEA sent a second letter to each of the RICO Supply Chain Claim Co-Conspirators on December 27, 2007, which implored them to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The letter further explained:

The regulation also requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant. Filing a monthly report of completed transactions (e.g., “excessive purchase report” or “high unity purchases”) does not meet the regulatory requirement to report suspicious orders. Registrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. *Registrants must conduct an independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted.*

See Letter from Joseph T. Rannazzisi, Deputy Assistant Adm’r, Office of Diversion Control, Drug. Enf’t Admin., U.S. Dep’t of Justice, to Cardinal Health (Dec. 27, 2007), filed in Cardinal Health, Inc. v. Holder, No. 1:12-cv- 00185-RBW (D.D.C. Feb. 10, 2012), ECF No. 14-8 (emphasis added).

likely to increase drastically from one year to the next, if a company *could expand the indications for use of a particular drug*, then it could boost sales exponentially without any real change in the country's health demography.”<sup>54</sup> And, without a new and robust primary market, there would be no supply for the secondary “spill-over” diversionary market that they intended.<sup>55</sup>

124. Once exposed, users of the opioids could easily transition into the secondary market, which was necessarily supplied from the primary market, and which Purdue and its co-conspirators were legally charged with ensuring there was no supply for. Soon, the demand from the secondary market was further driving prescriptions written for the primary market.<sup>56</sup>

**F. A New Primary Market of Prescriptions Opiates for Chronic, Widespread, Pain and Without Dose Limits**

125. Thus began Purdue and its RICO Marketing Claim co-conspirators' quest to open a new primary market for opioid prescriptions: treatment of (a) chronic, (b) widespread pain (c) without dose limits. And, their “ace in the hole” was this: not only could they change the standard of care so that physicians would write prescriptions into this new market, they could ensure through the insidious mechanism of addiction that patients, including pregnant women and women of child-bearing age, would have to keep coming back for more. High availability “correlates” with increased diversion and addiction.

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<sup>54</sup> Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Pacific Standard, March 4, 2015, found at: <http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company> (last visited Oct. 17, 2018).

<sup>55</sup> The axiomatic nature of this relationship is recognized in Dr. Art Van Zee's examination of the OxyContin market: “The high availability of OxyContin correlated with the increased abuse, diversion, and addiction, and by 2004 OxyContin had become a leading drug of abuse in the United States.” *See The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am. J. Pub. Health. 2009 February; 99(2): 221-227.

<sup>56</sup> However, in order to maintain the highly profitable and ever-growing secondary market, the Distributor Defendants also had to conceal the true facts relating to the supply of opiates flooding the primary market. Without the silence and concealment of the Distributor and Pharmacy Defendants, the dual market scheme (and record profits) could not have existed.

126. With the insidious power to create both unlimited supply AND unlimited demand for these highly addictive substances, Purdue and its co-conspirators set out to create the new primary market. Each of the elements of the new primary market were selected to maximize sales of the highly addictive drugs.

127. First, was the transition from a limited pool of disease and injury (cancer, disorders requiring surgery, etc.) to *widespread, common diseases*, such as arthritis, back pain, and joint pain. Thus, the universe of targeted patient conditions could be vastly expanded. Next was the successful promotion of highly addictive opioids for *chronic*, i.e., long-term conditions. Thus, step two was equally critical: ensuring that the newly targeted patient conditions would not result in one-time sales. And, finally, to ensure even further sales growth, Purdue and its co-conspirators promoted the notion that there were *no dose limits* and, indeed, that *patients who appeared to be addicted were actually patients who should be given even more and higher dosages for opioids*.<sup>57</sup>

128. In order to maximize profits, Purdue and its RICO Marketing Claim co-conspirators changed the standard of care throughout the United States by convincing physicians to expand treatment of their patients to include chronic and “non-malignant”, i.e., non-cancer, pain.<sup>58</sup> And, they had to do so despite the fact that while the benefits of opioids are minimal, and the extreme risks are maximal. Prospective, randomized, controlled trials lasting at least 4 weeks that evaluated

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<sup>57</sup> As previously stated, OxyContin was approved in 1996 for an 80mg dose and only four years later, Purdue sought and obtained FDA approval for a 160 mg dose was made it a “popular street drug” “comparable to heroin.” Mike Mariani, *How the American Opiate Epidemic Was Started by One Pharmaceutical Company*, Pacific Standard, March 4, 2015, found at: <http://theweek.com/articles/541564/how-american-opiate-epidemic-started-by-pharmaceutical-company> (last visited Oct. 17, 2018).

<sup>58</sup> The science and consensus for the use of opioids in the treatment of acute pain or pain associated with cancer is “robust,” due to the obvious nature of the risk/benefit analysis. Acute usage does not result in addiction. And, in cancer patients, the benefits from pain abatement greatly outweigh the known risks.

the use of opioids for chronic non-cancer-related pain showed only a small to modest improvement in pain relief and no consistent improvement in physical functioning.<sup>59</sup> The maximal adverse risks, however, are a witches' brew and include a "high incidence of opioid abuse behaviors" and "addiction."<sup>60</sup>

129. The market innovator that "inspired" its co-conspirators to collectively change the standard of care was Purdue, the maker of OxyContin. And, it was not pharmacological innovation in which it led, but marketing innovation. Indeed, this history of marketing innovations was chronicled by the investigative journalist Mike Mariani in 2015, when he highlighted these dubious accomplishments:

Arthur Sackler [the founder of Purdue, along with his two younger brothers Mortimer and Raymond] thriv[ed] . . . in the fledgling field of pharmaceutical advertising. It was here that he would leave his greatest mark. As a member of . . . a small New York-based advertising firm, Sackler expanded the possibilities of medical advertising by promoting products in medical journals and experimenting with televisions and radio marketing. Perhaps his greatest achievement, detailed in his biography in the Medical Advertising Hall of Fame, was finding enough different uses for Valium to turn it into the first drug to hit \$100 million in revenue. . . .

Sackler was also among the first medical advertisers to foster relationships with doctors in the hopes of earning extra points for his company's drugs, according to a 2011 expose in *Fortune*. Such backscratching in the hopes of reciprocity is now the model for the whole drug marketing industry.

Starting in 1996, Purdue Pharma expanded its sales department to coincide with the debut of its new drug. . . . Purdue increased its number of sales representatives from 318 in 1996 to 371 in 2000. By 2001, when OxyContin was hitting its stride, these sales reps received annual bonuses averaging over \$70,000, with some

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<sup>59</sup> Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (summarizing the results of thirteen medical studies cited at fns. 24-38).

<sup>60</sup> *Id.*

bonuses nearing a quarter of a million dollars. In that year, Purdue Pharma spent \$200 million marketing its golden goose.

Boots on the ground was not the only stratagem employed by Purdue to increase sales for OxyContin. Long before the rise of big data, Purdue was compiling profiles of doctors and their prescribing habits into databases. ...

Between physician databases, incentive-happy sales reps, and an aggressive blitz package of promotional ephemera, Purdue's multifaceted marketing campaign pushed OxyContin out of the niche offices of oncologists and pain specialists and into the primary care bazaar, where prescriptions for the drug could be handed out to millions upon millions of Americans. The most scathing irony is that what allowed OxyContin to reach so many households and communities was the claim that it wasn't dangerous.<sup>61</sup>

130. Concurrent with the innovative marketing techniques of Purdue, were the efforts of the entire industry to secure a highly potent and stable supply of the active pharmaceutical ingredient (API) in opioids. Upon information and belief, Janssen (which is defined to include the related company J&J) actively conspired with Purdue and its other co-conspirators to significantly increase the supply of powerful opioid drugs in the market, thereby exacerbating the opioid epidemic.<sup>62</sup> In a quest to dominate the growing opioid market, J&J grew poppies in Tasmania, Australia, and imported and sold APIs derived from these poppies necessary for the manufacture of opioid drugs to other Purdue and its co-conspirators.<sup>63</sup>

131. Beginning in 1990 and continuing until at least 2016, two wholly-owned subsidiaries, Noramco and Tasmanian Alkaloids Limited ("Tasmanian Alkaloids"), of J&J

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<sup>61</sup> Mike Mariani, "How the American Opiate Epidemic Was Started by One Pharmaceutical Company," *Pacific Standard*, March 4, 2015.

<sup>62</sup> Findings of Fact Nos. 6 through 15, *State of Oklahoma, et al. v. Purdue Pharma L.P.*, (Cause No. CJ-2017-816, Dist. Ct. of Cleveland Co., Oklahoma, Balkman, J.) (Judgment after Non-Jury Trial of August 26, 2019).

<sup>63</sup> *Id.* at Findings of Fact Nos. 9 through 11.

supplied opioid manufacturers with raw ingredients necessary to meet the growing demand for powerful opioid drugs as the opioid epidemic increased in severity.<sup>64</sup>

132. As the opioid crisis worsened, Tasmanian Alkaloids engaged in the cultivation, breeding, and processing of opium poppy plants into compounds necessary for the production of opioid APIs in Tasmania. These raw ingredients were then imported to the United States by Noramco.<sup>65</sup>

133. Noramco imported the raw ingredients produced by Tasmanian Alkaloids to the United States, processed the raw ingredients into opioid APIs, and sold these APIs to opioid manufacturers.<sup>66</sup>

134. J&J's activities in the production of raw opioid APIs included the development of the Norman Poppy, a strain of the plant containing high levels of the compound *Thebaine*, which is a critical ingredient for the production of oxycodone, oxymorphone, nalbuphine, naloxone, naltrexone, and buprenorphine.<sup>67</sup> The high-Thebaine Norman Poppy was patented by Tasmanian Alkaloids in 1994 and was a transformational technology that enabled the growth of pharmaceutical opioids.<sup>68</sup>

135. Noramco sold opioid APIs to various other opioid manufacturers, including Teva and “all seven of the top US generic companies,” through “long-term agreements. By 2016, when J&J transferred Noramco and Tasmanian Alkaloids to a private investment firm, Noramco was one of the nation’s top suppliers of opioid APIs. In a 2015 presentation to potential buyers of the

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<sup>64</sup> *Id.* at Finding of Fact No. 11.

<sup>65</sup> *Id.* at Findings of Fact Nos. 9 through 11.

<sup>66</sup> *Id.* at Finding of Fact No. 12.

<sup>67</sup> Finding of Fact Nos. 14, *State of Oklahoma, et al. v. Purdue Pharma L.P.*, (Cause No. CJ-2017-816, Dist. Ct. of Cleveland Co., Oklahoma, Balkman, J.) (Judgment after Non-Jury Trial of August 26, 2019).

<sup>68</sup> *Id.* at Finding of Fact No. 11.

company, Noramco was described to potential buyers as the “#1 supplier of Narcotic APIs in the United States, the world’s largest market.” The same presentation lists “Net Trade Sales” for several of Noramco’s APIs, including \$94 million in Oxycodone and \$52 million in hydrocodone in 2014 alone.

136. J&J’s supply of raw opioid ingredients enabled Purdue and its co-conspirators to meet the growing demand for powerful and dangerous opioid drugs formed in the wake of the pharmaceutical industry’s misleading mass marketing of opioid drugs to the medical community and directly to the public. By enabling the large-scale manufacture of these drugs, Janssen/J&J conspired with Purdue to create an opioid epidemic, addicting millions of Americans to opioid drugs and significantly increasing instances of NAS in the U.S.

**G. The Secondary Market**

137. As discussed at *supra*, “Controlled Substances and the ‘Closed System’ of Manufacturing and Distribution,” Purdue and its co-conspirators had an absolute and non-delegable duty to insure that a supply of controlled substances for a secondary market did not exist. To be clear, the diversion and misuse of controlled substances is a known high-risk factor with significant negative consequences for addiction. When a manufacturer or distributor that wants to deal in controlled substances registers with the DEA, they must take on a duty to prevent the known negative health effects of their addictive products.

138. In the case of prescription opiates, not only did Purdue and its co-conspirators wholly fail in that duty, but they intentionally endeavored to flood the primary market with such an excess of drugs that they either knew, or consciously and willfully disregarded the fact that this would result in misuse and diversion into a secondary market. **Indeed, Purdue and its co-**

**conspirators flooded the United States with so many prescription opiates that our entire adult population could be dosed 6 times a day for a month.<sup>69</sup>**

139. And, as will be shown, flooding an entire country with this many highly addictive opiates did not occur by accident. Instead, it occurred as the result of a highly coordinated, expensive, misleading, illegal, and callous manipulation of both the sales and distribution schemes for controlled substances within the United States.

#### **H. The Multi-Faceted Marketing and Promotion Schemes**

140. Purdue and its RICO Marketing co-conspirators have each conducted, and have continued to conduct, a scheme of marketing and promotion designed to persuade doctors that opioids can and should be used for chronic pain, thereby resulting in opioid treatment for a far broader group of patients who are much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. That these efforts were widely successful is evidenced by sales increases. Nationwide, from 1996 to 2002, there was a 226%, 73%, and 402% increase in fentanyl, morphine, and oxycodone prescribing respectively.<sup>70</sup> And, during that same period, misuse burgeoned. Hospital emergency department mentions for fentanyl, morphine, and oxycodone increased 641%, 113%, and 346%, respectively.<sup>71</sup>

141. In connection with this scheme, Purdue and its RICO Marketing co-conspirators spent millions of dollars each year on promotional activities and materials that falsely denied or

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<sup>69</sup> By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 mgs of hydrocodone every 4 hours for 1 month. Keyes KM, et al., *Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States*, Am J Public Health. 2014 Feb; 104(2):52-9.

<sup>70</sup> Gilson AM, et al., *A reassessment of trends in the medical use and abuse of opioid analgesics and implications for diversion control: 1997-2002*. J Pain Symptom Manage. 2004 Aug; 28(2):176-88.

<sup>71</sup> *Id.*

trivialized the risks of opioids while overstating the benefits of using them for chronic pain. These false and misleading promotional claims: (1) downplayed the serious risk of addiction; (2) created and promoted the concept of “pseudoaddiction” when signs of actual addiction began appearing and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence and withdrawal could be easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of “abuse-deterrent” opioid formulations to prevent abuse and addiction.

142. None of these marketing efforts disclosed, or even mentioned, the significant adverse health effects of opioids to unborn children. (This information was also available to Purdue’s RICO Supply Chain co-conspirators). Indeed, Purdue and its co-conspirators purposely misrepresented that there were no teratogenic effects associated with the use of opioids to increase their profits. Purdue and its co-conspirators also purposely misrepresented the potential of opioids to result in the negative health impacts from *in utero exposure* as described in this complaint.

143. Purdue and its co-conspirators also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no scientifically reliable evidence to support Purdue and its co-conspirators’ claims.

144. Purdue and its co-conspirators disseminated these common messages to reverse the previously held medical understanding of risks and benefits of opioid use and to improperly change the standard of care.<sup>72</sup> They disseminated these messages directly, through their sales

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<sup>72</sup> The “positive” physical effects of opioids are two-fold: euphoria and pain-relief. (However, medical doctors may not prescribe, nor will insurance pay, solely so that a patient may feel euphoric as that is not a medical need.) Thus, the valid medical basis for prescribing opiates is to allay pain. While temporary relief of pain is a positive, this result must absolutely be weighed

representatives, in speaker groups led by physicians Purdue and its co-conspirators recruited for their support of their marketing messages, and through unbranded marketing and industry-funded front groups.

145. Purdue's efforts to promote OxyContin are illustrative of the multi-faceted promotional scheme waged by the entire industry to improperly change the standard of care. An article by Dr. Art Van Zee in the AMERICAN JOURNAL OF PUBLIC HEALTH explored the breadth and depth of these efforts by Purdue:

From 1996 to 2001, Purdue conducted more than **40 national pain-management and speaker-training conferences at resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expense paid symposia, where they were recruited for Purdue's national speaker bureau.** It is well-documented that this type of pharmaceutical company symposium influences physicians' prescribing patterns, even though the physicians who attend such symposia believe that such enticements do not alter their prescribing patterns.

One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing. **Drug companies compile prescriber profiles on individual physicians—detailing the prescribing patterns of physicians nationwide—in an effort to influence doctors' prescribing habits. Through these profiles, a drug company can identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.** One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country. The resulting database would help identify physicians with large numbers of chronic-pain patients. Unfortunately, the same database would also identify which physicians were simply the most frequent prescribers of opioids and, in some cases, the least discriminate prescribers.

A lucrative bonus system encouraged sales **representatives** to increase sales of OxyContin in their territories, resulting in a large

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against the potential for negative outcomes. In the case of opioids the known potential negative outcome is iatrogenic addiction.

number of visits to physicians with high rates of opioid prescriptions, as well as a multifaceted information campaign aimed at them... Purdue paid \$40 million in sales incentive bonuses to its sales representatives that year.

From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671 **and [doubled] its total physician call list . . . to approximately 70,500 to 94,00 physicians. Through the sales representatives, Purdue used a patient starter coupon that provided patients with a free limited-time prescription for a 7-30 day supply.**<sup>73</sup> **By 2001, when the program was ended, approximately 34,000 had been redeemed nationally. . . .**

Purdue trained its sales representatives to carry the message that the risk of addiction was “less than one percent.” The company cited ... [two studies to support this premise]. Both of these studies, although shedding some light of the risk of addiction for acute pain, do not help establish the risk of iatrogenic addiction when opioids are used daily for a prolonged time in treating chronic pain. There are a number of studies [enough cites seven which looked at chronic usage], however, that demonstrate that in the treatment of chronic non-cancer-related pain with opioids, there is a high incidence of prescription drug abuse.

From 1996 to July 2002, **Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants, providing a venue that had enormous influence on physicians prescribing throughout the county.** Particularly, with controlled drugs, the potential for blurring marketing and education carries a much higher public health risk than with uncontrolled drugs.<sup>74</sup>

## **I. Two Lies: Minimizing Risks and Maximizing Benefits Minimizing Risks**

### **1. Minimizing Risks**

146. To falsely assure physicians and patients that opioids are safe, Purdue and its co-conspirators deceptively trivialized and failed to disclose the risks of long-term opioid use,

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<sup>73</sup> Yes, that’s right. A free coupon for a highly addictive controlled substance.

<sup>74</sup> Van Zee A. The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy. Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added).

particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations—which are described below—reinforced each other and created the dangerously misleading impression to improperly change the standard of care that: (1) starting patients on opioids was low risk because most patients would not become addicted, and because those at greatest risk for addiction could be identified and managed; (2) patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; (3) the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and (4) abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Purdue and its co-conspirators have not only failed to correct these misrepresentations, they continue to make them today.

147. Opioid manufacturers, including Purdue and Defendant Endo, have entered into settlement agreements with public entities that prohibit them from making many of the misrepresentations identified in this Complaint. Yet even afterward, Purdue and its co-conspirators continued to misrepresent the risks and benefits of long-term opioid use and each continues to fail to correct its past misrepresentations.

148. Some illustrative examples of Purdue and its co-conspirators' false, deceptive, and unfair written representations about the purportedly low risk of addiction include:<sup>75</sup>

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<sup>75</sup> Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added), citing Irick, N., *Overcoming Barriers to Effective Pain Management* [audiotape]. Rochester, NY: Solutions Unlimited; March 2000. See also Carr, B., *The Impact of Chronic Pain—An Interdisciplinary Perspective*, Continuing Medical Education program. New York, NY: Power-Pak Communications; 2000; 925 Program 424-000-99-010-H01; Lipmann, A., *Use of Opioids in Chronic Noncancer Pain*. Continuing Medical Education program. New York, NY: Power-Pak Communications; April 2000:6; *Pain Management* [CD and slide instructional program for

- a. Purdue created literature and audiotapes for physicians and a “Partners Against Pain” Website in which it claimed over and over that the risk of addiction from OxyContin was extremely small.
- b. Cephalon and Purdue sponsored the American Pain Foundation’s “Treatment Options: A Guide for People Living with Pain” (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online.<sup>76</sup>
- c. Endo sponsored a website, “PainKnowledge,” which, upon information and belief, claimed in 2009 that “[p]eople who take opioids as prescribed usually do not become addicted.” Upon information and belief, another Endo website, PainAction.com, stated “Did you Know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.” Endo also distributed an “Informed Consent” document on PainAction.com that misleadingly suggested that only people who “have problems with substance abuse and addiction” are likely to become addicted to opioid medications.
- d. Upon information and belief, Endo distributed a pamphlet with the Endo logo entitled “Living with Someone with Chronic Pain,” which stated that: “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.”

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physicians]. Stamford, CT: Purdue Pharma; 2002; *Dispelling the Myths about Opioids* [brochure for physicians]. Stamford, CT: Purdue Pharma; 2002.

<sup>76</sup> Am. Pain Found., *Treatment Options: A Guide for People Living in Pain* (2007) [hereinafter “APF Treatment Options”], found at: <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Oct. 17, 2018).

- e. Janssen reviewed, edited, approved, and distributed a patient education guide entitled “Finding Relief: Pain Management for Older Adults” (2009), which described as “myth” the claim that opioids are addictive, and asserted as fact that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.”
- f. Janssen currently runs a website, Prescriberresponsibly.com (last updated July 2, 2015), which claims that concerns about opioid addiction are “overestimated.”
- g. Purdue sponsored APF’s A Policymaker’s Guide to Understanding Pain & Its Management, which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to “[m]isconceptions about opioid addiction.”<sup>77</sup>
- h. Actavis’s predecessor caused a patient education brochure, “Managing Chronic Back Pain,” to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is “less likely if you have never had an addiction problem.” Based on Actavis’s acquisition of its predecessor’s marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

149. Consistent with Purdue and its co-conspirators’ published marketing materials, upon information and belief, sales representatives for Purdue, Endo, Janssen, and Cephalon minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the

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<sup>77</sup> Am. Pain Found., A Policymaker’s Guide to Understanding Pain and Its Management 6 (2011) [hereinafter “APF, Policymaker’s Guide”], available at: <http://s3.documentcloud.org/documents/277603/apf-policy-makers-guide.pdf> (last visited: Oct. 17, 2018).

potential for abuse of opioids with purportedly abuse-deterrent formulations; and routinely did not correct the misrepresentations noted above. Of these efforts, Dr. Art Van Zee writes: “Purdue trained its sales representatives to carry the message that the risk of addiction ‘was less than one percent.’”

150. These claims are contrary to longstanding scientific evidence. A 2016 opioid-prescription guideline issued by the CDC (the “2016 CDC Guideline”) explains that there is “[e]xtensive evidence” of the “possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction], [and] overdose . . .).”<sup>78</sup> The 2016 CDC Guideline further explains that “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” and that “continuing opioid therapy for 3 months substantially increases risk for opioid use disorder.”<sup>79</sup>

151. The FDA further exposed the falsity of Purdue and its co-conspirators’ claims about the low risk of addiction when it announced changes to the labels for extended-release and long-acting (“ER/LA”) opioids in 2013 and for immediate release (“IR”) opioids in 2016. In its announcement, the FDA found that “most opioid drugs have ‘high potential for abuse’” and that opioids “are associated with a ***substantial risk*** of misuse, abuse, ***NOWS [neonatal opioid withdrawal syndrome]***, addiction, overdose, and death.” (Emphasis added.) According to the FDA, because of the “known serious risks” associated with long-term opioid use, including “risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death,” opioids should be used only “in patients for whom alternative treatment

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<sup>78</sup> Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], available at: <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> (last visited Oct. 17, 2018).

<sup>79</sup> *Id.* at 2, 25.

options” like non-opioid drugs have failed.<sup>80</sup>

152. The State of New York, in a 2016 settlement agreement with Endo, found that opioid “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder.”<sup>81</sup> Endo had claimed on its [www.opana.com](http://www.opana.com) website that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted,” but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to “make statements that . . . opioids generally are non-addictive” or “that most patients who take opioids do not become addicted” in New York. Endo remains free, however, to make those statements elsewhere.

153. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing Purdue and its co-conspirators also fostered a fundamental misunderstanding of the signs of addiction. Specifically, Purdue and its co-conspirators misrepresented to doctors and patients that warning signs and/or symptoms of addiction were, instead, signs of undertreated pain (i.e.,

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<sup>80</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), available at: [http://paindr.com/wp-content/uploads/2013/09/FDA\\_CDOR\\_Response\\_to\\_Physicians\\_for\\_Responsible\\_Opioid\\_Prescribing\\_Partial\\_Petition\\_Approval\\_and\\_Denial.pdf](http://paindr.com/wp-content/uploads/2013/09/FDA_CDOR_Response_to_Physicians_for_Responsible_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf) (last visited Oct. 17, 2018); Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep’t of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (formerly available on U.S. Government website, but removed at an unknown date).

<sup>81</sup> Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 13 (March 1, 2016), available at: [https://ag.ny.gov/pdfs/Endo\\_AOD\\_030116-Fully\\_Executed.pdf](https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf) (last visited Oct. 17, 2018).

pseudoaddiction) —and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

154. To this end, one of Purdue’s employees, Dr. David Haddox, invented a phenomenon called “pseudoaddiction.” A paid industry “Key Opinion Leader” (KOL)<sup>82</sup> Dr. Russell Portenoy popularized the term. Examples of the false, misleading, deceptive, and unfair statements regarding pseudoaddiction include:

- a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007), which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.<sup>83</sup> The 2012 edition, which remains available for sale online, continues to teach that pseudoaddiction is real.<sup>84</sup>
- b. Janssen sponsored, funded, and edited the “Let’s Talk Pain” website, which in 2009 stated: “pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated... Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.”
- c. Endo sponsored a National Initiative on Pain Control (“NIPC”) CME program in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While

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<sup>82</sup> As physicians must choose from a myriad of drug options to treat their patients, they often rely on fellow physicians perceived as having superior knowledge in the area. These “Key Opinion Leaders” are ferreted out through a data-driven profiling system, and then targeted by pharmaceutical companies to promote certain drugs. The KOLs can both help spread information about the drug and expand markets. Indeed, the cultivation and management of KOLs is seen by the pharmaceutical industry wholly as a “business function.”

<sup>83</sup> Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2007) at 62.

<sup>84</sup> See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Physician’s Guide* (2d ed. 2012).

Maximizing Analgesia,” which, upon information and belief, promoted pseudoaddiction by teaching that a patient’s aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials.

- d. Purdue published a pamphlet in 2011 entitled Providing Relief, Preventing Abuse, which, upon information and belief, described pseudoaddiction as a concept that “emerged in the literature” to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated.”
- e. Upon information and belief, Purdue sponsored a CME program titled “Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse.” In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or “overindulges in unapproved escalating doses.” The doctor treats this patient by prescribing a high-dose, long-acting opioid.

155. In the 2016 CDC Guideline, the CDC rejected the validity of the pseudoaddiction fallacy invented by a Purdue employee as a reason to push more opioid drugs onto already-addicted patients.

156. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, a third category of false, deceptive, and unfair practices is Purdue and its co-

conspirators' false instructions that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Purdue and its co-conspirators aimed them at general practitioners and family doctors who lacked the time and expertise to closely manage higher-risk patients on opioids. Purdue and its co-conspirators' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Examples include:

- a. Endo paid for a 2007 supplement in the Journal of Family Practice written by a doctor who became a member of Endo's speakers bureau in 2010. The supplement, entitled Pain Management Dilemmas in Primary Care: Use of Opioids, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.
- b. Purdue, upon information and belief, sponsored a 2011 webinar, "Managing Patient's Opioid Use: Balancing the Need and Risk," which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."
- c. As recently as 2015, upon information and belief, Purdue represented in scientific conferences that "bad apple" patients—and not opioids—are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

157. The 2016 CDC Guideline confirms the falsity of these claims. The Guideline

explains that there are no studies assessing the effectiveness of risk mitigation strategies “for improving outcomes related to overdose, addiction, abuse or misuse.”<sup>85</sup>

158. A fourth category of misleading messaging regarding dangerous opioids is Purdue and its co-conspirators’ false assurances regarding the alleged ease of eliminating opioid dependence. Purdue and its co-conspirators falsely claimed that opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a problem, but they failed to disclose the increased difficulty of stopping opioids after long-term use. Purdue and its co-conspirators nonetheless downplayed the severity of opioid detoxification. For example:

- a. Upon information and belief, a CME sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10 days.
- b. And Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “[s]ymptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation” without mentioning any hardships that might occur.<sup>86</sup>

159. A fifth category of inaccurate statements Purdue and its co-conspirators made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was *critical* to Purdue and its co-conspirators’ efforts to market opioids for long-term use to treat chronic pain (and improperly change the standard of care) because, absent this misrepresentation, doctors would have abandoned treatment when patients build up tolerance and lower dosages did not provide pain relief. Purdue and its co-conspirators’ deceptive claims

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<sup>85</sup> *Id.* at 11.

<sup>86</sup> APF, *Policymaker’s Guide*, *supra* note 59, at 32.

include:

- a. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.<sup>87</sup> This publication is still available online.
- b. Endo sponsored a website, "Pain Knowledge," which, upon information and belief, claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."
- c. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM- 0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased ... You won't 'run out' of pain relief."<sup>88</sup>
- d. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- e. Upon information and belief, Purdue's "In the Face of Pain" website promoted the notion that if a patient's doctor does not prescribe what, in the patient's

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<sup>87</sup> *Id.* at 12.

<sup>88</sup> Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K Portenoy, M.D., ed., 2004).

view, is a sufficient dosage of opioids, he or she should find another doctor who will.

- f. Actavis's predecessor caused a patient education brochure, "Managing Chronic Back Pain," to be distributed beginning in 2003 that admitted that opioid addiction is possible, but falsely claimed that it is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.
- g. Purdue sponsored APF's "A Policymaker's Guide to Understanding Pain & Its Management," which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.<sup>89</sup>
- h. In 2007, Purdue sponsored a CME entitled "Overview of Management Options" that was available for CME credit and available until at least 2012. The CME was edited by a KOL and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.
- i. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.<sup>90</sup>

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<sup>89</sup> APF, *Policymaker's Guide*, *supra* note 59, at 32.

<sup>90</sup> The College on Problems of Drug Dependence, About the College, <http://cpdd.org> (last visited Aug. 21, 2017).

- j. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, Purdue and its co-conspirators' Front Groups APF and NFP argued in an amicus brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.<sup>91</sup>

160. Once again, the 2016 CDC Guideline reveals that Purdue and its co-conspirators' representations regarding opioids were lacking in scientific evidence. The 2016 CDC Guideline clarifies that the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage."<sup>92</sup> More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages."<sup>93</sup> The CDC also states that there is an increased risk "for opioid use disorder, respiratory depression, and death at higher dosages."<sup>94</sup> That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.<sup>95</sup>

161. Purdue and its co-conspirators' inaccurate marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions in the medical community that these opioids can cure addiction and abuse. Purdue and its co-conspirators made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush-resistant, in a way that suggested it was more difficult to abuse. This

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<sup>91</sup> Brief of the American Pain Foundation, the National Pain Foundation, and the National Foundation for the Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474 (4th Cir. Sept. 8, 2005) [hereinafter Brief of APF] at 9.

<sup>92</sup> 2016 CDC Guideline, *supra* note 60, at 22–23.

<sup>93</sup> *Id.* at 23-24.

<sup>94</sup> 2016 CDC Guideline, *supra* note 60, at 21.

<sup>95</sup> *Id.* at 16.

claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets’ “extended-release features can be compromised, causing the medication to ‘dose dump,’ when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing.”<sup>96</sup> Also troubling, Opana ER can be prepared for snorting using commonly available methods and “readily prepared for injection.”<sup>97</sup> The letter discussed “the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection.”<sup>98</sup> Endo’s own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market

## **2. Maximizing the Benefits, Especially as Compared to other Non-Addictive Alternatives**

162. To convince doctors that opioids should be used to treat chronic pain, Purdue and its co-conspirators also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC Guideline makes clear, “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later (with most placebo-controlled randomized trials  $\leq$  6 weeks in duration)” and that other treatments were more or equally beneficial and less harmful than long-term opioid use.<sup>99</sup> The FDA, too, has recognized the lack of evidence to support long-term opioid use. Despite this, Purdue and its co-conspirators falsely and misleadingly touted the benefits of long-term opioid use

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<sup>96</sup> Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin. U.S. Dep’t of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5, available at: [https://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/May/FDA\\_CDOR\\_Final\\_RespEndo\\_Pharmaceuticals\\_Inc\\_Petition\\_Denial.pdf](https://www.pharmamedtechbi.com/~media/Supporting%20Documents/The%20Pink%20Sheet%20DAILY/2013/May/FDA_CDOR_Final_RespEndo_Pharmaceuticals_Inc_Petition_Denial.pdf) (last visited Oct. 17, 2018).

<sup>97</sup> *Id.* at 6.

<sup>98</sup> *Id.* at 6, n.21

<sup>99</sup> *Id.* at 5.

and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

163. Examples of Purdue and its co-conspirators' false claims are:

- a. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.
- b. Janssen sponsored and edited a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009) —which states as “a fact” that “opioids may make it easier for people to live normally.” The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.
- c. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of presumed patients in active professions; the caption read, “Pain doesn't fit into their schedules.”
- d. Upon information and belief, Purdue ran a series of advertisements for OxyContin in 2012 in medical journals entitled “Pain vignettes,” which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function.
- e. Responsible Opioid Prescribing (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function.
- f. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which counseled patients that opioids “give [pain

patients] a quality of life we deserve.”<sup>100</sup> This publication is still available online.

- g. Endo’s NIPC website “PainKnowledge” claimed in 2009 that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” Elsewhere, the website touted improved quality of life (as well as “improved function”) as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make misleading claims about function, and Endo closely tracked visits to the site.
- h. Endo was the sole sponsor, through NIPC, of a series of CMEs entitled “Persistent Pain in the Older Patient.”<sup>101</sup> Upon information and belief, a CME disseminated via webcast claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.”
- i. Janssen sponsored and funded a multimedia patient education campaign called “Let’s Talk Pain.” One feature of the campaign was to complain that patients were under-treated. In 2009, upon information and belief, a Janssen-sponsored website, part of the “Let’s Talk Pain” campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to “continue to function.”
- j. Purdue sponsored the development and distribution of APF’s “A Policymaker’s

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<sup>100</sup> APF, Treatment Options, *supra* note 58 at 15, NIPC, Persistent Pain and the Older Patient (2007), available at: <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Oct. 17, 2018).

<sup>101</sup> *Id.* at 1.

Guide to Understanding Pain & Its Management, which claimed that “[m]ultiple clinical studies” have shown that opioids are effective in improving “[d]aily function,” “[p]sychological health,” and “[o]verall health-related quality of life for chronic pain.”<sup>102</sup> The Policymaker’s Guide was originally published in 2011.

- k. Purdue, Cephalon, Endo, and Janssen’s sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

164. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature. In 2010, the FDA warned Actavis, in response to its advertising of Kadian described above, that “we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient’s work, physical and mental functioning, daily activities, or enjoyment of life.”<sup>103</sup> In 2008, upon information and belief, the FDA sent a warning letter to an opioid manufacturer, making it clear “that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience.”

165. Purdue and its co-conspirators also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, so that doctors would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Purdue and its co-

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<sup>102</sup> APF, Policymaker’s Guide, *supra* note 59, at 29.

<sup>103</sup> Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc’ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), [hereinafter Letter from Thomas Abrams to Doug Boothe], available at: <https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last visited Oct. 17, 2018).

conspirators contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort “in patients for which alternative treatment options” like non-opioid drugs “are inadequate.” And, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the first-line treatment for chronic pain, particularly arthritis and lower back pain.<sup>104</sup>

166. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours – a fact that Purdue has known at all times relevant to this action. Upon information and belief, Purdue’s own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it. This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

167. Purdue’s competitors were aware of this problem. For example, upon information and belief, Endo ran advertisements for Opana ER referring to “real” 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours.

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<sup>104</sup> 2016 CDC Guideline, *supra* note 60, at 12.

168. Front Groups supported by Purdue likewise echoed these representations. For example, in an *amicus* brief submitted to the Supreme Court of Ohio by the American Pain Foundation, the National Foundation for the Treatment of Pain and the Ohio Pain Initiative in support of Purdue, those amici represented:

OxyContin is particularly useful for sustained long-term pain because it comes in higher, compact pills with a slow release coating. OxyContin pills can work for 12 hours. This makes it easier for patients to comply with dosing requirements without experiencing a roller-coaster of pain relief followed quickly by pain renewal that can occur with shorter acting medications. It also helps the patient sleep through the night, which is often impossible with short-acting medications. For many of those serviced by Pain Care Amici, OxyContin has been a miracle medication.<sup>105</sup>

169. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of “serious and life-threatening adverse events” and abuse—which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.<sup>106</sup> Specifically, the FDA

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<sup>105</sup> Reply Brief of *Amicus Curiae* of the American Pain Foundation, The National Foundation for the Treatment of Pain and the Ohio Pain Initiative Supporting Appellants, *Howland v. Purdue Pharma L.P.*, No. 2003-1538 (Ohio Apr. 13, 2004), 2004 WL 1637768, at \*4 (footnote omitted).

<sup>106</sup> See U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), (page no longer available at the FDA website).

advised that Fentora “is only approved for breakthrough cancer pain in patients who are opioid-tolerant, meaning those patients who take a regular, daily, around-the-clock narcotic pain medication.”<sup>107</sup>

170. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example:

- a. Cephalon paid to have a CME it sponsored, Opioid-Based Management of Persistent and Breakthrough Pain, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that “[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain.
- b. Upon information and belief, Cephalon’s sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.
- c. In December 2011, Cephalon widely disseminated a journal supplement entitled “Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology News,

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<sup>107</sup> *Id.*

and Pain Medicine News—three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for “multiple causes of pain” —and not just cancer pain.

171. Cephalon’s deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

**J. Purdue and its co-conspirators Targeted Susceptible Prescribers and their Vulnerable Patient Populations, Including Pregnant Women and Women of Child-Bearing Years**

172. As a part of their deceptive marketing scheme, Purdue and its co-conspirators identified and targeted susceptible prescribers with vulnerable patient populations in the United States, including pregnant women and women of child-bearing years. Women are prescribed significantly more opioids than men. *Indeed, in 2010, the Centers for Disease Control found that one-third of pregnant women in the United States were prescribed an opioid during pregnancy.*<sup>108</sup> Purdue has sold billions of pills to women of childbearing age and pregnant women and extracted massive profits as a result. *One of the primary addiction routes for women of child-bearing age is to have been first prescribed opioids at childbirth which is an especially vulnerable period given their likely strained mental and physical condition, such that by the time they have additional children, they have become addicts.* Purdue and its co-conspirators focused their marketing on primary care doctors who were more likely to treat chronic pain patients, the majority of whom were women, and prescribe them drugs but were less likely to be educated about treating pain and

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<sup>108</sup> See, e.g., Desai, R., “Increase in Prescription Opioid Use during Pregnancy among Medicaid Enrolled Women,” OBSTET. GYNECOL., 2014 May; 123(5): 997-1002 (examining the increase in opioid dosing to pregnant women from 2000-2007).

the risks and benefits of opioids and, therefore, more likely to accept Purdue and its co-conspirators' misrepresentations.

173. Purdue and its co-conspirators also targeted prescribers for vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Purdue and its co-conspirators targeted these vulnerable patient prescribers even though the risks of long-term opioid use were significantly greater for them. For example, the 2016 CDC Guideline observes that existing evidence confirms that elderly patients taking opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages.<sup>109</sup> The 2016 CDC Guideline concludes that there must be “additional caution and increased monitoring” to minimize the risks of opioid use in elderly patients. *Id.* at 27. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

174. *Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Indeed, it capitalized on this failure by transforming it into a marketing opportunity.* Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue

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<sup>109</sup> 2016 CDC Guideline, *supra* note 60, at 13.

failed to take action—even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue’s district manager described it internally as “an organized drug ring” until years after law enforcement shut it down. In doing so, Purdue protected its own profits at the expense of public health and safety.<sup>110</sup>

175. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing, and upon information and belief, actually capitalized on the information via increased marketing to suspicious prescribers. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

**K. Purdue and Its Co-conspirators Made False Statements and Concealed Material Facts**

176. As alleged herein, Purdue and its co-conspirators made and/or disseminated false statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. Purdue and its co-conspirators’ actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

**1. Purdue**

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<sup>110</sup> Harriet Ryan et al., *More Than 1 Million Oxycontin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew*, L.A. Times, July 10, 2016, available at: <http://www.latimes.com/projects/la-me-oxycontin-part2/> (last visited Oct. 17, 2018).

177. Purdue made and/or disseminated false statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers;
- b. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- c. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- d. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- e. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- f. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- g. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose- dependent risks of opioids versus NSAIDs;
- h. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- i. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- j. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- k. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- l. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- m. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- n. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain,

including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- o. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and
- p. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.
- q. Making deceptive statements concerning the appropriateness of the use of Purdue opioid medications to treat neck and back and other chronic pain conditions without disclosing the lack of approval and lack of evidence for such uses;
- r. Creating literature and audiotapes for physicians and a “Partners Against Pain” Website in which it claimed over and over that the risk of addiction from OxyContin was extremely small.<sup>111</sup>

178. Since its launch, Purdue aggressively worked to grow its profits through illegal and misleading tactics, including its reimbursement-related tactics. These schemes resulted in the

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<sup>111</sup> Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added), citing Irick, N., Overcoming Barriers to Effective Pain Management [audiotape]. Rochester, NY: Solutions Unlimited; March 2000; Carr, B., The Impact of Chronic Pain—An Interdisciplinary Perspective, Continuing Medical Education program. New York, NY: Power-Pak Communications; 2000; 925 Program 424-000-99-010-H01; Lipmann, A., Use of Opioids in Chronic Noncancer Pain. Continuing Medical Education program. New York, NY: Power-Pak Communications; April 2000; 6; Pain Management [CD and slide instructional program for physicians]. Stamford, CT: Purdue Pharma; 2002; Dispelling the Myths about Opioids [brochure for physicians]. Stamford, CT: Purdue Pharma; 2002.

increased prescription of Purdue's dangerous opioids onto patients who did not need them as a result in the changed standard of care.

179. Purdue incentivized its sales force to engage in illegal and misleading conduct. Many of the Purdue sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded representatives more for selling higher (and more expensive) doses of Oxycontin. This was a "highly unusual" practice because dosing was a patient-specific decision usually made by a doctor.

## **2. Endo**

180. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral,

intranasal, or intravenous abuse;

- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Funding and directing pro-opioid pain organizations (including over \$5 million to the organization responsible for many of the most egregious misrepresentations) that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- j. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- k. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of

pseudoaddiction;

- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- m. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

181. Par Pharmaceutical is an affiliate of Endo, which manufactures opioids sold throughout the United States. All allegations pertaining to Endo also apply to Par Pharmaceutical. Moreover, Par Pharmaceutical is a manufacturer, and all allegations against Purdue and its co-conspirators herein apply equally to Par Pharmaceutical.

### **3. Janssen**

182. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and

promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;
- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long- term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- i. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- j. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and

efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- k. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

183. Regarding the conduct of these entities, an Oklahoma State District Court found:

This court has found that sufficient evidence has been presented in this case to support a finding that Jansen engaged in misleading marketing activities that resulted in a substantial increase in the supply of prescription opioids and proximately caused harm to Plaintiffs. Additionally, this court has found that the record presented so far in this case could allow a jury to reasonably conclude that Janssen's unbranded marketing efforts were a substantial factor in producing the harm alleged by Plaintiffs. Further, this court has found that evidence has been produced upon which a jury could reasonably conclude that Janssen failed to maintain effective controls against diversion, and that these failures were a substantial factor in producing the harm suffered by Plaintiffs.

*See* Opinion and Order Denying Janssen's Motion for Summary Judgment, Case 1:17-md-02804-DAP, Doc #2567, filed 09/09/2019.

184. Dr. Paul Janssen, the founder of Janssen Pharmaceutica, originally invented fentanyl in the 1950s. Fentanyl, an extremely powerful opioid, is a major factor in the opioid crisis, related to rising numbers of overdose deaths as well as the increasing prevalence of NAS. *See* Finding of Fact No. 5, Judgment After Non-Jury Trial in *Oklahoma v. Johnson & Johnson*, Case No. CJ-2017-816.

185. Additionally, misinformation from Janssen's direct marketing to doctors influenced the medical community's prescribing practices and perception of the dangers of opioids and encouraged doctors liberally and aggressively write a higher number of opioid prescriptions. The

rapid increase in the prescribing and sale of opioid drugs is directly and causally linked to negative consequences of the opioid epidemic including addiction and overdose deaths as well as rising rates of NAS and children entering the child welfare system. *See* Findings of Fact No. 53 and 55, Judgment After Non-Jury Trial in *Oklahoma v. Johnson & Johnson*, Case No. CJ-2017-816.

#### **4. Cephalon**

186. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;
- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

**5. Actavis**

187. Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer

pain and that opioids improve quality of life while concealing contrary data.

**L. Purdue and its RICO Marketing Claim Co-Conspirators Used Multiple Avenues to Disseminate Their False Statements about Opioid**

188. Purdue and its RICO Marketing Claim co-conspirators spread their misinformation detailed above by multiple channels, including by deployed seemingly unbiased and independent third parties that they controlled, including recruited speakers. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Purdue and its co-conspirators’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Purdue and its co-conspirators consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

189. Purdue and its co-conspirators also directly targeted marketing efforts of their branded opioids directly to doctors and patients in each of the fifty states. In fact, they specifically targeted susceptible prescribers and vulnerable patient populations. Purdue and its co-conspirators also deployed seemingly unbiased and independent third parties that they controlled to spread their false, reckless, and/or negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout susceptible and vulnerable geographic areas and patient populations, including pregnant women.

190. Purdue and its co-conspirators ensured marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Purdue and its co-conspirators’ sales representatives and physician speakers were

required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

**1. Direct Marketing**

191. Purdue and its RICO Marketing Claim co-conspirators' direct marketing of opioids generally proceeded on two tracks. First, they each conducted advertising campaigns touting the purported benefits of their branded drugs. For example, upon information and belief, Purdue and its co-conspirators spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

192. Many of Purdue and its co-conspirators' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website [Opana.com](http://Opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain Vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

193. Second, Purdue and its co-conspirators promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Purdue and its co-conspirators have not corrected this misinformation. Instead, they devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Purdue and its co-conspirators spent in excess of \$168

million on “detailing” branded opioids to doctors, more than twice what they spent on “detailing” in 2000.

194. Purdue and its co-conspirators’ “detailing” to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face “detailing” having the greatest influence. Even without such studies, Purdue and its co-conspirators purchased, manipulated and analyzed some of the most sophisticated data available in any industry, data available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allowed them to target, tailor, and monitor the impact of their core messages. Thus, Purdue and its co-conspirators knew their “detailing” to doctors is effective.

## **2. Indirect Marketing**

195. Purdue and its RICO Marketing Claim co-conspirators’ indirectly and collusively marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

196. Purdue and its co-conspirators deceptively marketed opioids throughout the United States through unbranded advertising—e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Purdue and its co-conspirators controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Purdue and its co-conspirators controlled the distribution of their “core messages” via their own “detailers” and speaker programs,

Purdue and its co-conspirators similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, Purdue and its co-conspirators used third-party public relations firms to help control those messages when they originated from third parties.

197. Purdue and its co-conspirators marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Purdue and its co-conspirators also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Purdue and its co-conspirators used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

198. Purdue and its co-conspirators also identified doctors to serve (for generous payment), on their speakers’ bureaus and to attend programs with speakers and meals paid for by Purdue and its co-conspirators. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Purdue and its co-conspirators. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Purdue and its co-conspirators’ prior misrepresentations about the risks and benefits of opioids. Borrowing a page from Big Tobacco’s playbook, Purdue and its co-conspirators worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS,

and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. Purdue and its co-conspirators then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly “neutral” guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Purdue and its co-conspirators persuaded doctors and patients that what they have long known—that opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and that the compassionate treatment of pain required opioids.

199. The Purdue “speakers’ program” was perhaps its most widespread and damaging scheme. It was a pay-to-prescribe program.

200. Purdue’s sham speakers’ program and other misleading and illegal tactics have been outlined in great detail in indictments and guilty pleas of Purdue executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

201. In 2007, three Purdue executives were indicted and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe and defraud insurance companies.

202. In 2007, multiple states sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promoting prescribing practices which have worsened the opioid crisis.

203. Pro-opioid doctors are one of the most important avenues that Purdue and its co-conspirators use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Purdue and its co-conspirators know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that doctors who provided testimonials on the site were paid by Purdue and concluded that Purdue’s failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

204. Purdue and its co-conspirators utilized many KOLs, including many of the same ones. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Purdue and its co-conspirators identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society (“APS”) / American Academy of Pain Medicine (“AAPM”) Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation (“APF”), an advocacy organization almost entirely funded by Purdue and its co-conspirators.

205. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that “the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.” He

appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”<sup>112</sup>

206. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”<sup>113</sup> Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did”.<sup>114</sup>

207. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unremarkable pain clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013. He is a Senior Editor of “Pain Medicine”, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Purdue and its co-conspirators (including nearly \$2 million from Cephalon).

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<sup>112</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

<sup>113</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, available at: <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (last visited Oct. 17, 2018).

<sup>114</sup> *Id.*

208. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses.

209. Ironically, Dr. Webster created and promoted the "Opioid Risk Tool," a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's "Opioid Risk Tool" appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the "Opioid Risk Tool" into their own guidelines, indicating also their reliance on Purdue and its co-conspirators and those under their influence and control.

210. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors throughout the United States.<sup>115</sup>

211. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings but as indications of undertreated

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<sup>115</sup> See "Emerging Solutions in Pain, Managing Patient's Opioid Use: Balancing the Need and the Risk," [http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com\\_continued&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209) (last visited Aug. 22, 2017).

pain. In Dr. Webster's description, the only way to differentiate the two was to increase a patient's dose of opioids. As he and co-author Beth Dove wrote in their 2007 book "Avoiding Opioid Abuse While Managing Pain"—a book that is still available online—when faced with signs of aberrant behavior, increasing the dose "in most cases . . . should be the clinician's first response."<sup>116</sup> Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."<sup>117</sup>

212. Purdue and its co-conspirators also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Purdue and its co-conspirators, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Purdue and its co-conspirators by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Purdue and its co-conspirators.

213. These Front Groups depended on Purdue and its co-conspirators for funding and, in some cases, for survival. Purdue and its co-conspirators also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Purdue and its co-conspirators made sure that the Front Groups would generate only the messages that Purdue and its co-conspirators wanted to

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<sup>116</sup> Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, MedGenMed. 2007; 9(4): 2 (2007).

<sup>117</sup> John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

214. Purdue and its co-conspirators Cephalon, Endo, and Janssen, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including APS, American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).<sup>118</sup>

215. The most prominent of Purdue and its co-conspirators’ Front Groups was APF which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes— including death – among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to target all 50 states.

216. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received

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<sup>118</sup> See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. On Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2017), [https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20\(5%20May%202017\).pdf](https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf) (last visited May 31, 2018).

about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Purdue and its co-conspirators Cephalon, Endo, and others to avoid using its line of credit.

217. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide “patient representatives” for Purdue and its co-conspirators’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” APF functioned largely as an advocate for the interests of Purdue and its co-conspirators, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in non-profit organizations that share [its] business interests.”

218. Plaintiffs are informed, and believe, that on several occasions, representatives of Purdue and its co-conspirators, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

219. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party, and Purdue and its co-conspirators stopped funding it. Within

days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."<sup>119</sup>

220. Another front group for Purdue and its co-conspirators was AAPM. With the assistance, prompting, involvement, and funding of Purdue and its co-conspirators, AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to Purdue and its co-conspirators' deceptive marketing of chronic opioid therapy.

221. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at offsite dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Purdue and its co-conspirators Endo and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

222. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone.

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<sup>119</sup> Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Tied to Pain Groups*, Wash. Post, May 8, 2012, available at: [https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU\\_story.html?utm\\_term=.b9627ff19557](https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?utm_term=.b9627ff19557) (last visited Oct. 17, 2018).

AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

223. Purdue and its co-conspirators were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

224. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.<sup>120</sup>

225. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.<sup>121</sup> Treatment guidelines have been relied upon by doctors, especially general practitioners and family doctors targeted by Purdue and its co-conspirators. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, will and Purdue discussed treatment guidelines with doctors during individual sales visits.

226. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from

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<sup>120</sup> *The use of opioids for the treatment of chronic pain. A consensus statement from the American Academy of Pain Medicine and the American Pain Society.* Clin J Pain. 1997 Mar; 13(1):6-8.

<sup>121</sup> Chou R, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain.* J Pain. 2009 Feb; 10(2):113-30.

Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.<sup>122</sup>

227. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Purdue and its co-conspirators, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated throughout the United States during the relevant time period, are still available online, and were reprinted in the Journal of Pain. Purdue and its co-conspirators widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or Purdue and its co-conspirators financial support to members of the panel.

228. Purdue and its co-conspirators worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Purdue and its co-conspirators combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Purdue and its co-conspirators. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably

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<sup>122</sup> *Id.*

negative and did not require mandatory participation by prescribers, which Purdue and its co-conspirators determined would reduce prescribing.

**M. Purdue and its RICO Marketing Claim Co-conspirators Misrepresented Their Misconduct**

229. Purdue and its RICO Marketing Claims co-conspirators, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes, including NAS. The FDA warned Purdue and its co-conspirators of this, and Purdue and its co-conspirators had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of NAS, addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Purdue and its co-conspirators' misrepresentations, and Endo and Purdue entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

230. At all times relevant to this Complaint, Purdue and its co-conspirators took steps to conceal and misrepresent their deceptive marketing and unlawful and unfair conduct. For example, Purdue and its co-conspirators disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Purdue and its co-conspirators purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Purdue and its co-conspirators' false and deceptive statements about the risks and benefits of long-term opioid use

for chronic pain. Purdue and its co-conspirators also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Purdue and its co-conspirators exerted considerable influence on these promotional and “educational” materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Purdue and its co-conspirators, including Janssen, ran similar websites that masked their own role.

231. Finally, Purdue and its co-conspirators manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. Purdue and its co-conspirators distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. Purdue and its co-conspirators invented “pseudoaddiction” and promoted it to an unsuspecting medical community. Purdue and its co-conspirators provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Purdue and its co-conspirators recommended to the medical community that dosages be increased, without disclosing the risks. Purdue and its co-conspirators spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

**N. Purdue and its RICO Marketing Claim and RICO Supply Chain Co-conspirators’  
Abject Failure to Maintain the Closed System of Manufacturing and Distribution**

232. Concurrent with their promotional and marketing campaign, opioid manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their

shared legal duty with distributors both to investigate and notify authorities of all suspected diversions of these highly dangerous substances.

233. Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Purdue and its co-conspirators engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Purdue and its RICO Marketing Claim co-conspirators knew the volume, frequency, and pattern of opioid orders being placed and filled. Purdue and its co-conspirators built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

234. Federal statutes and regulations are clear: just like opioid distributors (and pharmacies), opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

235. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.<sup>123</sup>

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<sup>123</sup> See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million

236. In the press release accompanying the settlement, the Department of Justice stated:

Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone... Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.]<sup>124</sup>

237. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”<sup>125</sup>

238. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”<sup>126</sup>

239. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone

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Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), available at: <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders> (last visited Oct. 17, 2018).

<sup>124</sup> *Id.*

<sup>125</sup> *Id.*

<sup>126</sup> *Id.*

products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

1. conduct adequate due diligence of its customers;
2. detect and report to the DEA orders of unusual size and frequency;
3. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
4. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
5. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
6. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware; iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.<sup>127</sup>

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<sup>127</sup> Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 2-3 (July 10, 2017) [hereinafter 2017 Mallinckrodt MOA], available at: <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (last visited Oct. 17, 2018).

240. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”<sup>128</sup>

241. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to “downstream” registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”<sup>129</sup>

242. The same duties imposed by federal law on Mallinckrodt were imposed upon Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators.

243. The same business practices utilized by Mallinckrodt regarding “chargebacks” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, Purdue and its other co-conspirators. Through, inter alia, the chargeback data, Purdue and

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<sup>128</sup> *Id.* at 3-4.

<sup>129</sup> *Id.* at 5.

its co-conspirators could monitor suspicious orders of opioids. Purdue and its co-conspirators failed to monitor, report, and halt suspicious orders of opioids as required by federal law. Purdue and its co-conspirators' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful. Purdue and its co-conspirators have misrepresented their compliance with federal law.

244. The wrongful actions and omissions of Purdue and its co-conspirators which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's claims below.

245. Purdue and its co-conspirators' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

**O. Purdue and its RICO Marketing Claim and RICO Supply Chain Co-conspirators Were on Notice of and Failed to Stop the Illegal Diversion of Opiates**

246. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, Purdue's RICO Supply Chain co-conspirators Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90% of all revenues from drug distribution in the United States—an estimated \$378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, who then dispense the drugs to patients.

247. Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

248. For example, at the wholesale level of distribution, diversion occurs whenever distributors and/or pharmacies allow opioids to be lost or stolen in transit, or when distributors and/or pharmacies fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

249. Plaintiffs and the Class have been significantly damaged by the effects of Purdue and its co-conspirators' opioid diversion.

250. Purdue and its co-conspirators have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

251. In addition to having common law duties, Purdue and its co-conspirators are governed by the statutory requirements of the CSA, 21 U.S.C. § 801 *et seq.* and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. Purdue and its co-conspirators' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. Purdue and its co-conspirators' repeated, unabashed, and prolific violations of these requirements show that they have acted in total and reckless disregard.

252. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of

[controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

253. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a “registration” with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

254. All opioid manufacturers and distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, manufacturers and distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

255. To prevent unauthorized users from obtaining opioids, the CSA creates a monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA’s Automation of Reports and Consolidation Orders System (“ARCOS”) is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on the manufacture of controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled

substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

256. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

257. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

258. To maintain registration, manufacturers and distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a registrant has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 C.F.R. § 1301.71.

259. For years, Purdue and its co-conspirators have known of the problems and consequences of opioid diversion in the supply chain and have committed repeated violations of

the laws and regulations of the United States as cited above, consequently making them liable under various federal and state laws.

260. To combat the problem of opioid diversion, the DEA has provided guidance to registrants, including Purdue and its co-conspirators, on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with registrants regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided registrants with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The registrants were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the “red flags” registrants should look for to identify potential diversion.

261. Since 2007, the DEA has hosted no less than five conferences to provide registrants with updated information about opioid diversion trends. Purdue and its co-conspirators attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association, now the HDA. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

262. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registrants, including Purdue and its co-conspirators, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

263. The September 27, 2006, letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a registrant when attempting to make a determination if the order is indeed suspicious.

264. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including Purdue and its co-conspirators, providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that

filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

265. The HDMA, Purdue and its co-conspirators' own industry group, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

266. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

267. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

268. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity" (emphasis added).

269. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

270. In addition to the obligations imposed by law, through their own words, representations, and actions, Purdue and its co-conspirators have voluntarily undertaken a duty to

protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, Purdue and its co-conspirators have miserably and negligently failed.

271. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

272. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

273. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

274. Relying on state laws and regulations, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations. Although distributors, including Purdue and its co-conspirators, have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

275. Purdue and its co-conspirators have supplied massive quantities of prescription opioids throughout the United States with the actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Purdue and its co-conspirators negligently or intentionally failed to do so.

276. Purdue and its co-conspirators knew or should have known that the amount of opioids that they discharged into the supply chain was far in excess of what could be consumed for medically necessary purposes in the relevant communities (especially given that each co-conspirator knew it was not the only entity servicing those communities).

277. Purdue and its co-conspirators did not adequately control their supply lines to prevent diversion. Manufacturers and distributors of Schedule II controlled substances are required to prevent opioid diversion and protect against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in the United States; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

278. On information and belief, Purdue and its co-conspirators made little to no effort to visit the pharmacies to perform due diligence inspections to ensure that the controlled substances Purdue and its co-conspirators had furnished were not being diverted to illegal uses.

279. On information and belief, the compensation that Purdue and its co-conspirators provided to certain of their employees was affected, in part, by the volume of their sales of opioids, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

280. It was reasonably foreseeable to Purdue and its co-conspirators that their conduct in flooding the consumer markets of the United States with highly addictive opioids would allow opioids to fall into the hands of women of child-bearing years, as well as women who were already pregnant. Thus, it is reasonably foreseeable to Purdue and its co-conspirators that, when unintended users gain access to opioids, tragic preventable injuries will result, including neonatal

addiction and NAS and a new and substantially different burden of care for the Legal Guardians of the NAS Children.

281. Purdue and its co-conspirators knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

282. Purdue and its co-conspirators knew or should have known that a substantial amount of the opioids dispensed in the United States were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids would cause harm to individual Plaintiffs, the putative Class, and the NAS Children for whom they care.

283. Purdue and its co-conspirators were aware of widespread prescription opioid abuse in the United States, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in certain geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purpose in those areas.

284. Purdue and its co-conspirators could and should have taken action that: (a) limited to 7 days supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed. If Purdue and its co-conspirators had adhered to effective controls to guard against diversion, the Class would have avoided harm.

285. Purdue and its co-conspirators made substantial profits over the years based on the diversion of opioids. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiffs and the Class. Purdue and its co-conspirators knew full well that Plaintiff Legal Guardians and the Class would be unjustly forced to bear these injuries and damages.

286. The Distributor and Pharmacy Purdue and its co-conspirators' intentional distribution of excessive amounts of prescription opioids to communities showed an intentional or reckless disregard for Plaintiff legal Guardians and the Class. Their conduct poses a continuing economic threat to the Legal Guardians who must care for the welfare of the NAS Children.

**P. Facts Specific to the RICO Claims**

**1. Purdue and Its Co-conspirators Made False Statements and Concealed Material Facts**

287. As alleged herein, Purdue and its co-conspirators made and/or disseminated false statements regarding material facts and further concealed material facts, in the course of manufacturing, marketing, and selling prescription opioids. Purdue and its co-conspirators' actions were intentional and/or unlawful. Such statements include, but are not limited to, those set out below and alleged throughout this Complaint.

**a. Purdue**

288. Purdue made and/or disseminated false statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Withholding from law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its opioid, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same

prescribers;

- b. Creating, sponsoring, and assisting in the distribution of patient education materials distributed to consumers that contained deceptive statements;
- c. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- d. Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- e. Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;
- f. Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- g. Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose- dependent risks of opioids versus NSAIDs;
- h. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- i. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- j. Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;
- k. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- l. Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- m. Assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic noncancer pain;
- n. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long- term efficacy;
- o. Exclusively disseminating misleading statements in education materials to hospital doctors and staff while purportedly educating them on new pain standards; and
- p. Making deceptive statements concerning the use of opioids to treat chronic non-

cancer pain to prescribers through in-person detailing.

- q. Making deceptive statements concerning the appropriateness of the use of Purdue opioid medications to treat neck and back and other chronic pain conditions without disclosing the lack of approval and lack of evidence for such uses;
- r. Creating literature and audiotapes for physicians and a “Partners Against Pain” Website in which it claimed over and over that the risk of addiction from OxyContin was extremely small.<sup>130</sup>

289. Since its launch, Purdue aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. These fraudulent and misleading schemes resulted in the increased prescription of Purdue’s dangerous opioids onto patients who did not need them.

290. Purdue incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Purdue sales representatives were new to the pharmaceutical industry and their base salaries were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded representatives more for selling higher (and more

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<sup>130</sup> Van Zee A., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, Am J Public Health. 2009 Feb; 99(2):221-27 (emphasis added), citing Irick, N., Overcoming Barriers to Effective Pain Management [audiotape]. Rochester, NY: Solutions Unlimited; March 2000; Carr, B., The Impact of Chronic Pain—An Interdisciplinary Perspective, Continuing Medical Education program. New York, NY: Power-Pak Communications; 2000; 925 Program 424-000-99-010-H01; Lipmann, A., Use of Opioids in Chronic Noncancer Pain. Continuing Medical Education program. New York, NY: Power-Pak Communications; April 2000;6; Pain Management [CD and slide instructional program for physicians]. Stamford, CT: Purdue Pharma; 2002; Dispelling the Myths about Opioids [brochure for physicians]. Stamford, CT: Purdue Pharma; 2002.

expensive) doses of Oxycontin. This was a “highly unusual” practice because dosing was a patient-specific decision usually made by a doctor.<sup>131</sup>

**b. Endo**

291. Defendant Endo made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- c. Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high risk patients;
- d. Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo’s opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- e. Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo’s own unbranded publications and on internet sites Endo sponsored or operated;
- f. Endorsing, directly distributing, and assisting in the distribution of publications

that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- g. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- h. Funding and directing pro-opioid pain organizations (including over \$5 million to the organization responsible for many of the most egregious misrepresentations) that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- i. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- j. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- k. Directly distributing and assisting in the dissemination of literature written by pro- opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- l. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for

long-term efficacy; and

- m. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

292. Par Pharmaceutical is an affiliate of Endo, which manufactures opioids sold throughout the United States. All allegations pertaining to Endo also apply to Par Pharmaceutical. Moreover, Par Pharmaceutical is a manufacturer, and all allegations against Purdue and its co-conspirators herein apply equally to Par Pharmaceutical.

**c. Janssen**

293. Defendant Janssen made and/or disseminated deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;
- c. Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;
- d. Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- e. Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;
- f. Providing significant financial support to pro-opioid KOLs, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- h. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- i. Directly distributing and assisting in the dissemination of literature written by pro-opioid KOLs that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;
- j. Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and
- k. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing.

**d. Cephalon**

294. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- b. Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;
- c. Providing significant financial support to pro-opioid KOL doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;
- e. Funding and directing pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- f. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- g. Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;
- h. Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine

specialists, and workers' compensation programs, serving chronic pain patients;

- i. Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and
- j. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing and speakers' bureau events.

**e. Actavis**

295. Actavis made and/or disseminated deceptive statements and concealed material facts in such a way to make their statements deceptive, including but not limited to the following:

- a. Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to prescribers through in-person detailing;
- b. Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;
- c. Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and
- d. Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

**Q. Purdue and its RICO Marketing Claim Co-Conspirators Used Multiple Avenues to Disseminate Their False Statements about Opioid**

296. Purdue and its RICO Marketing Claim co-conspirators spread their misinformation detailed above by multiple channels, including by deployed seemingly unbiased and independent

third parties that they controlled, including recruited speakers. Across the pharmaceutical industry, “core message” development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Purdue and its co-conspirators’ messages are accurately and consistently delivered across marketing channels—including detailing visits, speaker events, and advertising—and in each sales territory. Purdue and its co-conspirators consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

297. Purdue and its co-conspirators also directly targeted marketing efforts of their branded opioids directly to doctors and patients in each of the fifty states. In fact, they specifically targeted susceptible prescribers and vulnerable patient populations. Purdue and its co-conspirators also deployed seemingly unbiased and independent third parties that they controlled to spread their false, reckless, and/or negligent statements about the risks and benefits of opioids for the treatment of chronic pain throughout susceptible and vulnerable geographic areas and patient populations, including pregnant women.

298. Purdue and its co-conspirators ensured marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons (the company employees who respond to physician inquiries); centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Purdue and its co-conspirators’ sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.

# **1. Direct Marketing**

299. Purdue and its RICO Marketing Claim co-conspirators’ direct marketing of opioids generally proceeded on two tracks. First, they each conducted advertising campaigns touting the

purported benefits of their branded drugs. For example, upon information and belief, Purdue and its co-conspirators spent more than \$14 million on medical journal advertising of opioids in 2011, nearly triple what they spent in 2001.

300. Many of Purdue and its co-conspirators' branded ads deceptively portrayed the benefits of opioids for chronic pain. For example, Endo distributed and made available on its website [Opana.com](http://Opana.com) a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like construction worker, chef, and teacher, misleadingly implying that the drug would provide long-term pain-relief and functional improvement. Upon information and belief, Purdue also ran a series of ads, called "Pain Vignettes," for OxyContin in 2012 in medical journals. These ads featured chronic pain patients and recommended OxyContin for each. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would help the writer work more effectively.

301. Second, Purdue and its co-conspirators promoted the use of opioids for chronic pain through "detailers"—sales representatives who visited individual doctors and medical staff in their offices—and small-group speaker programs. Purdue and its co-conspirators have not corrected this misinformation. Instead, they devoted massive resources to direct sales contacts with doctors. Upon information and belief, in 2014 alone, Purdue and its co-conspirators spent in excess of \$168 million on "detailing" branded opioids to doctors, more than twice what they spent on "detailing" in 2000.

302. Purdue and its co-conspirators' "detailing" to doctors is effective. Numerous studies indicate that marketing impacts prescribing habits, with face-to-face "detailing" having the greatest influence. Even without such studies, Purdue and its co-conspirators purchased, manipulated and analyzed some of the most sophisticated data available in any industry, data

available from IMS Health Holdings, Inc., to track, precisely, the rates of initial prescribing and renewal by individual doctor, which in turn allowed them to target, tailor, and monitor the impact of their core messages. Thus, Purdue and its co-conspirators knew their “detailing” to doctors is effective.

## **2. Indirect Marketing**

303. Purdue and its RICO Marketing Claim co-conspirators’ indirectly and collusively marketed their opioids using unbranded advertising, paid speakers and “key opinion leaders” (“KOLs”), and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as “Front Groups”).

304. Purdue and its co-conspirators deceptively marketed opioids throughout the United States through unbranded advertising—e.g., advertising that promotes opioid use generally but does not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Purdue and its co-conspirators controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Purdue and its co-conspirators controlled the distribution of their “core messages” via their own “detailers” and speaker programs, Purdue and its co-conspirators similarly controlled the distribution of these messages in scientific publications, treatment guidelines, Continuing Medical Education (“CME”) programs, and medical conferences and seminars. To this end, Purdue and its co-conspirators used third-party public relations firms to help control those messages when they originated from third parties.

305. Purdue and its co-conspirators marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not

reviewed by the FDA. Purdue and its co-conspirators also used third-party, unbranded advertising to give the false appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Purdue and its co-conspirators used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

306. Purdue and its co-conspirators also identified doctors to serve (for generous payment), on their speakers' bureaus and to attend programs with speakers and meals paid for by Purdue and its co-conspirators. These speaker programs provided: (1) an incentive for doctors to prescribe a particular opioid (so they might be selected to promote the drug); (2) recognition and compensation for the doctors selected as speakers; and (3) an opportunity to promote the drug through the speaker to his or her peers. These speakers give the false impression that they are providing unbiased and medically accurate presentations when they are, in fact, presenting a script prepared by Purdue and its co-conspirators. On information and belief, these presentations conveyed misleading information, omitted material information, and failed to correct Purdue and its co-conspirators' prior misrepresentations about the risks and benefits of opioids. Borrowing a page from Big Tobacco's playbook, Purdue and its co-conspirators worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors who served as KOLS, and (b) funding, assisting, directing, and encouraging seemingly neutral and credible Front Groups. Purdue and its co-conspirators then worked together with those KOLs and Front Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, CME programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and KOLs, Purdue and its co-conspirators persuaded doctors and patients that what they have long known—that

opioids are addictive drugs, unsafe in most circumstances for long-term use—was untrue, and that the compassionate treatment of pain required opioids.

307. The Purdue “speakers’ program” was perhaps its most widespread and damaging scheme. It was a pay-to-prescribe program.

308. Purdue’s sham speakers’ program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Purdue executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

309. In 2007, three Purdue executives were indicted and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe and defraud insurance companies.

310. In 2007, multiple states sued Purdue for engaging in unfair and deceptive practices in its marketing, promotion, and sale of OxyContin. Certain states settled their claims in a series of Consent Judgments that prohibited Purdue from making misrepresentations in the promotion and marketing of OxyContin in the future. By using indirect marketing strategies, however, Purdue intentionally circumvented these restrictions. Such actions include contributing to the creation of misleading publications and prescribing guidelines which lack reliable scientific basis and promoting prescribing practices which have worsened the opioid crisis.

311. Pro-opioid doctors are one of the most important avenues that Purdue and its co-conspirators use to spread their false and deceptive statements about the risks and benefits of long-term opioid use. Purdue and its co-conspirators know that doctors rely heavily and less critically on their peers for guidance, and KOLs provide the false appearance of unbiased and reliable support for chronic opioid therapy. For example, the State of New York found in its settlement with Purdue that the Purdue website “In the Face of Pain” failed to disclose that doctors who

provided testimonials on the site were paid by Purdue and concluded that Purdue's failure to disclose these financial connections potentially misled consumers regarding the objectivity of the testimonials.

312. Purdue and its co-conspirators utilized many KOLs, including many of the same ones. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York, is one example of a KOL whom Purdue and its co-conspirators identified and promoted to further their marketing campaign. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1996 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Purdue and its co-conspirators.

313. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations, such as his claim that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of

substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted.”<sup>132</sup>

314. Dr. Portenoy later admitted that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to “destigmatize” opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that “[d]ata about the effectiveness of opioids does not exist.”<sup>133</sup> Portenoy candidly stated: “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, . . . I guess I did”.<sup>134</sup>

315. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unremarkable pain clinic in Salt Lake City, Utah. Dr. Webster was President of AAPM in 2013. He is a Senior Editor of “Pain Medicine”, the same journal that published Endo special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Purdue and its co-conspirators (including nearly \$2 million from Cephalon).

316. During a portion of his time as a KOL, Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice’s Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster’s former patients at the Lifetree Clinic have died of opioid overdoses.

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<sup>132</sup> Good Morning America (ABC television broadcast Aug. 30, 2010).

<sup>133</sup> Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall St. J., Dec. 17, 2012, available at: <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (last visited Oct. 17, 2018).

<sup>134</sup> *Id.*

317. Ironically, Dr. Webster created and promoted the “Opioid Risk Tool,” a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster’s “Opioid Risk Tool” appear on, or are linked to, websites run by Endo, Janssen, and Purdue. Unaware of the flawed science and industry bias underlying this tool, certain states and public entities have incorporated the “Opioid Risk Tool” into their own guidelines, indicating also their reliance on Purdue and its co-conspirators and those under their influence and control.

318. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled “Managing Patient’s Opioid Use: Balancing the Need and the Risk.” Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors throughout the United States.<sup>135</sup>

319. Dr. Webster also was a leading proponent of the concept of “pseudoaddiction,” the notion that addictive behaviors should be seen not as warnings but as indications of undertreated pain. In Dr. Webster’s description, the only way to differentiate the two was to increase a patient’s dose of opioids. As he and co-author Beth Dove wrote in their 2007 book “Avoiding Opioid Abuse While Managing Pain”—a book that is still available online—when faced with signs of aberrant

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<sup>135</sup> See “Emerging Solutions in Pain, Managing Patient’s Opioid Use: Balancing the Need and the Risk,” [http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com\\_continued&view=frontmatter&Itemid=303&course=209](http://www.emergingsolutionsinpain.com/ce-education/opioid-management?option=com_continued&view=frontmatter&Itemid=303&course=209) (last visited Aug. 22, 2017).

behavior, increasing the dose “in most cases . . . should be the clinician’s first response.”<sup>136</sup> Upon information and belief, Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too much of an excuse to give patients more medication.”<sup>137</sup>

320. Purdue and its co-conspirators also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Purdue and its co-conspirators, these “Front Groups” generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. They also assisted Purdue and its co-conspirators by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Purdue and its co-conspirators.

321. These Front Groups depended on Purdue and its co-conspirators for funding and, in some cases, for survival. Purdue and its co-conspirators also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Purdue and its co-conspirators made sure that the Front Groups would generate only the messages that Purdue and its co-conspirators wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members—whether patients suffering from pain or doctors treating those patients.

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<sup>136</sup> Lynn Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain*, MedGenMed. 2007; 9(4): 2 (2007).

<sup>137</sup> John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html>.

322. Purdue and its co-conspirators Cephalon, Endo, and Janssen, in particular, utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including APS, American Geriatrics Society (“AGS”), the Federation of State Medical Boards (“FSMB”), American Chronic Pain Association (“ACPA”), the Center for Practical Bioethics (“CPB”), the U.S. Pain Foundation (“USPF”) and Pain & Policy Studies Group (“PPSG”).<sup>138</sup>

323. The most prominent of Purdue and its co-conspirators’ Front Groups was APF which, upon information and belief, received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012, primarily from Endo and Purdue. APF issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. APF also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes— including death – among returning soldiers. APF also engaged in a significant multimedia campaign—through radio, television and the internet—to educate patients about their “right” to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to target all 50 states.

324. In 2009 and 2010, more than 80% of APF’s operating budget came from pharmaceutical industry sources. Including industry grants for specific projects, APF received about \$2.3 million from industry sources out of total income of about \$2.85 million in 2009; its

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<sup>138</sup> See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. On Fin., to Sec. Thomas E. Price, U.S. Dep’t of Health and Human Servs., (May 5, 2017), [https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20\(5%20May%202017\).pdf](https://www.finance.senate.gov/imo/media/doc/050817%20corrected%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group%20(5%20May%202017).pdf) (last visited May 31, 2018).

budget for 2010 projected receipts of roughly \$2.9 million from drug companies, out of total income of about \$3.5 million. By 2011, upon information and belief, APF was entirely dependent on incoming grants from Purdue and its co-conspirators Cephalon, Endo, and others to avoid using its line of credit.

325. APF held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. Upon information and belief, it was often called upon to provide “patient representatives” for Purdue and its co-conspirators’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” APF functioned largely as an advocate for the interests of Purdue and its co-conspirators, not patients. Indeed, upon information and belief, as early as 2001, Purdue told APF that the basis of a grant was Purdue’s desire to “strategically align its investments in non-profit organizations that share [its] business interests.”

326. Plaintiffs are informed, and believe, that on several occasions, representatives of Purdue and its co-conspirators, often at informal meetings at conferences, suggested activities and publications for APF to pursue. APF then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

327. The U.S. Senate Finance Committee began looking into APF in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to APF’s credibility as an objective and neutral third party, and Purdue and its co-conspirators stopped funding it. Within

days of being targeted by Senate investigation, APF's board voted to dissolve the organization "due to irreparable economic circumstances." APF "cease[d] to exist, effective immediately."<sup>139</sup>

328. Another front group for Purdue and its co-conspirators was AAPM. With the assistance, prompting, involvement, and funding of Purdue and its co-conspirators, AAPM issued purported treatment guidelines and sponsored and hosted medical education programs essential to Purdue and its co-conspirators' deceptive marketing of chronic opioid therapy.

329. AAPM received substantial funding from opioid manufacturers. For example, AAPM maintained a corporate relations council whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at offsite dinner symposia in connection with AAPM's marquee event—its annual meeting held in Palm Springs, California, or other resort locations. AAPM describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Purdue and its co-conspirators Endo and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event.

330. Upon information and belief, AAPM is viewed internally by Endo as "industry friendly," with Endo advisors and speakers among its active members. Endo attended AAPM conferences, funded its CMEs, and distributed its publications. The conferences sponsored by AAPM heavily emphasized sessions on opioids – 37 out of roughly 40 at one conference alone.

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<sup>139</sup> Charles Ornstein & Tracy Weber, *Senate Panel Investigates Drug Companies' Tied to Pain Groups*, Wash. Post, May 8, 2012, available at: [https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU\\_story.html?utm\\_term=.b9627ff19557](https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain-groups/2012/05/08/gIQA2X4qBU_story.html?utm_term=.b9627ff19557) (last visited Oct. 17, 2018).

AAPM's presidents have included top industry-supported KOLs Perry Fine and Lynn Webster. Dr. Webster was even elected president of AAPM while under a DEA investigation.

331. Purdue and its co-conspirators were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

332. In 1996, AAPM and APS jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patients' addiction to opioids was low. Dr. Haddox, who co-authored the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the sole consultant. The consensus statement remained on AAPM's website until 2011, and, upon information and belief, was taken down from AAPM's website only after a doctor complained.<sup>140</sup>

333. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS Guidelines") and continued to recommend the use of opioids to treat chronic pain.<sup>141</sup> Treatment guidelines have been relied upon by doctors, especially general practitioners and family doctors targeted by Purdue and its co-conspirators. Treatment guidelines not only directly inform doctors' prescribing practices but are cited throughout the scientific literature and referenced by third-party payors in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, will and Purdue discussed treatment guidelines with doctors during individual sales visits.

334. At least 14 of the 21 panel members who drafted the AAPM/APS Guidelines, including KOLs Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from

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<sup>140</sup> *The use of opioids for the treatment of chronic pain. A consensus statement from the American Academy of Pain Medicine and the American Pain Society.* Clin J Pain. 1997 Mar; 13(1):6-8.

<sup>141</sup> Chou R, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain.* J Pain. 2009 Feb; 10(2):113-30.

Janssen, Cephalon, Endo, and Purdue. The 2009 Guidelines promote opioids as “safe and effective” for treating chronic pain, despite acknowledging limited evidence, and conclude that the risk of addiction is manageable for patients regardless of past abuse histories.<sup>142</sup>

335. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 Guidelines were influenced by contributions that drug companies, including Purdue and its co-conspirators, made to the sponsoring organizations and committee members. These AAPM/APS Guidelines have been a particularly effective channel of deception and have influenced not only treating physicians but also the body of scientific evidence on opioids; the Guidelines have been cited hundreds of times in academic literature, were disseminated throughout the United States during the relevant time period, are still available online, and were reprinted in the Journal of Pain. Purdue and its co-conspirators widely referenced and promoted the 2009 Guidelines without disclosing the lack of evidence to support them or Purdue and its co-conspirators financial support to members of the panel.

336. Purdue and its co-conspirators worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, Purdue and its co-conspirators combined their efforts through the Pain Care Forum (“PCF”), which began in 2004 as an APF project. PCF is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from Purdue and its co-conspirators. Among other projects, PCF worked to ensure that an FDA-mandated education project on opioids was not unacceptably

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<sup>142</sup> *Id.*

negative and did not require mandatory participation by prescribers, which Purdue and its co-conspirators determined would reduce prescribing.

**R. Purdue and its RICO Marketing Claim Co-conspirators Misrepresented Their Misconduct**

337. Purdue and its RICO Marketing Claims co-conspirators, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes, including NAS. The FDA warned Purdue and its co-conspirators of this, and Purdue and its co-conspirators had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of NAS, addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Purdue and its co-conspirators' misrepresentations, and Endo and Purdue entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

338. At all times relevant to this Complaint, Purdue and its co-conspirators took steps to conceal and misrepresent their deceptive marketing and unlawful and unfair conduct. For example, Purdue and its co-conspirators disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and KOLs. Purdue and its co-conspirators purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Purdue and its co-conspirators' false and deceptive statements about the risks and benefits of long-term opioid use

for chronic pain. Purdue and its co-conspirators also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Purdue and its co-conspirators exerted considerable influence on these promotional and “educational” materials in emails, correspondence, and meetings with KOLs, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the NIPC, did not disclose Endo’s involvement. Purdue and its co-conspirators, including Janssen, ran similar websites that masked their own role.

339. Finally, Purdue and its co-conspirators manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. Purdue and its co-conspirators distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. Purdue and its co-conspirators invented “pseudoaddiction” and promoted it to an unsuspecting medical community. Purdue and its co-conspirators provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Purdue and its co-conspirators recommended to the medical community that dosages be increased, without disclosing the risks. Purdue and its co-conspirators spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids’ alleged benefits, disguising the risks, and promoting sales.

**S. Purdue and its RICO Marketing Claim and RICO Supply Chain Co-conspirators’  
Abject Failure to Maintain the Closed System of Manufacturing and Distribution**

340. Concurrent with their promotional and marketing campaign, opioid manufacturers exercised their unique and dangerous ability to create both a new supply AND a new demand (via addiction) for the product. They accomplished this by acting in concert and in abrogation of their

shared legal duty with distributors both to investigate and notify authorities of all suspected diversions of these highly dangerous substances.

341. Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators had access to and possession of the information necessary to monitor, report, and prevent suspicious orders and to prevent diversion. Purdue and its co-conspirators engaged in the practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a manufacturer to a distributor after the distributor sells the manufacturer’s product at a price below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for example, the distributor requests a chargeback from the manufacturer and, in exchange for the payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to which it sold the product. Thus, Purdue and its RICO Marketing Claim co-conspirators knew the volume, frequency, and pattern of opioid orders being placed and filled. Purdue and its co-conspirators built receipt of this information into the payment structure for the opioids provided to the opioid distributors.

342. Federal statutes and regulations are clear: just like opioid distributors (and pharmacies), opioid manufacturers are required to “design and operate a system to disclose . . . suspicious orders of controlled substances” and to maintain “effective controls against diversion.” 21 C.F.R. § 1301.74; 21 U.S.C. § 823(a)(1).

343. The Department of Justice has recently confirmed the suspicious order obligations clearly imposed by federal law upon opioid manufacturers, fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements.<sup>143</sup>

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<sup>143</sup> See Press Release, U.S. Dep’t of Justice, Mallinckrodt Agrees to Pay Record \$35 Million

344. In the press release accompanying the settlement, the Department of Justice stated:

Mallinckrodt did not meet its obligations to detect and notify DEA of suspicious orders of controlled substances such as oxycodone, the abuse of which is part of the current opioid epidemic. These suspicious order monitoring requirements exist to prevent excessive sales of controlled substances, like oxycodone... Mallinckrodt's actions and omissions formed a link in the chain of supply that resulted in millions of oxycodone pills being sold on the street. . . Manufacturers and distributors have a crucial responsibility to ensure that controlled substances do not get into the wrong hands[.]<sup>144</sup>

345. Among the allegations resolved by the settlement, the government alleged “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances – orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.”<sup>145</sup>

346. The Memorandum of Agreement entered into by Mallinckrodt (“2017 Mallinckrodt MOA”) avers “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.”<sup>146</sup>

347. The 2017 Mallinckrodt MOA further details the DEA’s allegations regarding Mallinckrodt’s failures to fulfill its legal duties as an opioid manufacturer:

With respect to its distribution of oxycodone and hydrocodone

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Settlement for Failure to Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations (July 11, 2017), available at: <https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders> (last visited Oct. 17, 2018).

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

products, Mallinckrodt's alleged failure to distribute these controlled substances in a manner authorized by its registration and Mallinckrodt's alleged failure to operate an effective suspicious order monitoring system and to report suspicious orders to the DEA when discovered as required by and in violation of 21 C.F.R. § 1301.74(b). The above includes, but is not limited to Mallinckrodt's alleged failure to:

1. conduct adequate due diligence of its customers;
2. detect and report to the DEA orders of unusual size and frequency;
3. detect and report to the DEA orders deviating substantially from normal patterns including, but not limited to, those identified in letters from the DEA Deputy Assistant Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007:
4. orders that resulted in a disproportionate amount of a substance which is most often abused going to a particular geographic region where there was known diversion,
5. orders that purchased a disproportionate amount of substance which is most often abused compared to other products, and
6. orders from downstream customers to distributors who were purchasing from multiple different distributors, of which Mallinckrodt was aware; iv. use “chargeback” information from its distributors to evaluate suspicious orders. Chargebacks include downstream purchasing information tied to certain discounts, providing Mallinckrodt with data on buying patterns for Mallinckrodt products; and v. take sufficient action to prevent recurrence of diversion by downstream customers after receiving concrete information of diversion of Mallinckrodt product by those downstream customers.<sup>147</sup>

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<sup>147</sup> Administrative Memorandum of Agreement between the United States Department of Justice, the Drug Enforcement Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC at 2-3 (July 10, 2017) [hereinafter 2017 Mallinckrodt MOA], available at: <https://www.justice.gov/usao-edmi/press-release/file/986026/download> (last visited Oct. 17, 2018).

348. Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion Control, to registrants dated September 27, 2006 and December 27, 2007.” Mallinckrodt further agreed that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product. Further, Mallinckrodt agrees to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”<sup>148</sup>

349. Mallinckrodt acknowledged that “[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors). The transaction information contains data relating to the direct customer sales of controlled substances to “downstream” registrants.” Mallinckrodt agreed that, from this data, it would “report to the DEA when Mallinckrodt concludes that the chargeback data or other information indicates that a downstream registrant poses a risk of diversion.”<sup>149</sup>

350. The same duties imposed by federal law on Mallinckrodt were imposed upon Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators.

351. The same business practices utilized by Mallinckrodt regarding “chargebacks” and receipt and review of data from opioid distributors regarding orders of opioids were utilized industry-wide among opioid manufacturers and distributors, including, upon information and belief, Purdue and its other co-conspirators. Through, inter alia, the chargeback data, Purdue and

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<sup>148</sup> *Id.* at 3-4.

<sup>149</sup> *Id.* at 5.

its co-conspirators could monitor suspicious orders of opioids. Purdue and its co-conspirators failed to monitor, report, and halt suspicious orders of opioids as required by federal law. Purdue and its co-conspirators' failures to monitor, report, and halt suspicious orders of opioids were intentional and unlawful. Purdue and its co-conspirators have misrepresented their compliance with federal law.

352. The wrongful actions and omissions of Purdue and its co-conspirators which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiff's claims below.

353. Purdue and its co-conspirators' actions and omissions in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the unlawful diversion of opioids throughout the United States.

**T. Purdue and its RICO Marketing Claim and RICO Supply Chain Co-conspirators Were on Notice of and Failed to Stop the Illegal Diversion of Opiates**

354. The supply chain for prescription opioids begins with the manufacture and packaging of the pills. The manufacturers then transfer the pills to distribution companies, Purdue's RICO Supply Chain co-conspirators Cardinal, McKesson, and AmerisourceBergen, which together account for 85-90% of all revenues from drug distribution in the United States—an estimated \$378.4 billion in 2015. The distributors then supply opioids to pharmacies, doctors, and other healthcare providers, who then dispense the drugs to patients.

355. Purdue and its RICO Marketing Claim and RICO Supply Chain co-conspirators share the responsibility for controlling the availability of prescription opioids. Opioid "diversion" occurs whenever the supply chain of prescription opioids is broken, and the drugs are transferred from a legitimate channel of distribution or use, to an illegitimate channel of distribution or use. Diversion can occur at any point in the opioid supply chain.

356. For example, at the wholesale level of distribution, diversion occurs whenever distributors and/or pharmacies allow opioids to be lost or stolen in transit, or when distributors and or pharmacies fill suspicious orders of opioids from buyers, retailers, or prescribers. Suspicious orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern, and/or orders of unusual frequency and duration.

357. Plaintiffs and the Class have been significantly damaged by the effects of Purdue and its co-conspirators' opioid diversion.

358. Purdue and its co-conspirators have a duty to exercise reasonable care under the circumstances. This involves a duty not to create a foreseeable risk of harm to others. Additionally, one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care to prevent the threatened harm.

359. In addition to having common law duties, Purdue and its co-conspirators are governed by the statutory requirements of the CSA, 21 U.S.C. § 801 *et seq.* and its implementing regulations. These requirements were enacted to protect society from the harms of drug diversion. Purdue and its co-conspirators' violations of these requirements show that they failed to meet the relevant standard of conduct that society expects from them. Purdue and its co-conspirators' repeated, unabashed, and prolific violations of these requirements show that they have acted in total and reckless disregard.

360. The CSA creates a legal framework for the distribution and dispensing of controlled substances. Congress passed the CSA partly out of a concern about "the widespread diversion of

[controlled substances] out of legitimate channels into the illegal market.” H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566, 4572.

361. Accordingly, the CSA acts as a system of checks and balances from the manufacturing level through delivery of the pharmaceutical drug to the patient or ultimate user. Every person or entity that manufactures, distributes, or dispenses opioids must obtain a “registration” with the DEA. Registrants at every level of the supply chain must fulfill their obligations under the CSA, otherwise controlled substances move from the legal to the illicit marketplace, and there is enormous potential for harm to the public.

362. All opioid manufacturers and distributors are required to maintain effective controls against opioid diversion. They are also required to create and use a system to identify and report downstream suspicious orders of controlled substances to law enforcement. Suspicious orders include orders of unusual size, orders deviating substantially from the normal pattern, and orders of unusual frequency. To comply with these requirements, manufacturers and distributors must know their customers, report suspicious orders, conduct due diligence, and terminate orders if there are indications of diversion.

363. To prevent unauthorized users from obtaining opioids, the CSA creates a monitoring system for controlled substances, including registration and tracking requirements imposed upon anyone authorized to handle controlled substances. The DEA’s Automation of Reports and Consolidation Orders System (“ARCOS”) is an automated drug reporting system that records and monitors the flow of Schedule II controlled substances from point of manufacture through commercial distribution channels to point of sale. ARCOS accumulates data on the manufacture of controlled substances, acquisition transactions, and distribution transactions, which are then summarized into reports used by the DEA to identify any diversion of controlled

substances into illicit channels of distribution. Each person or entity that is registered to distribute ARCOS Reportable controlled substances must report acquisition and distribution transactions to the DEA.

364. Acquisition and distribution transaction reports must provide data on each acquisition to inventory (identifying whether it is, e.g., by purchase or transfer, return from a customer, or supply by the Federal Government) and each reduction from inventory (identifying whether it is, e.g., by sale or transfer, theft, destruction or seizure by Government agencies) for each ARCOS Reportable controlled substance. 21 U.S.C. § 827(d) (l); 21 C.F.R. §§ 1304.33(e), (d). Inventory that has been lost or stolen must also be reported separately to the DEA within one business day of discovery of such loss or theft.

365. In addition to filing acquisition/distribution transaction reports, each registrant is required to maintain a complete, accurate, and current record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of. 21 U.S.C. §§ 827(a)(3), 1304.2l(a), 1304.22(b). It is unlawful for any person to negligently fail to abide by the recordkeeping and reporting requirements.

366. To maintain registration, manufacturers and distributors must also maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific and industrial channels. When determining if a registrant has provided effective controls, the DEA Administrator refers to the security requirements set forth in §§ 130 1.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. 21 C.F.R. § 1301.71.

367. For years, Purdue and its co-conspirators have known of the problems and consequences of opioid diversion in the supply chain and have committed repeated violations of

the laws and regulations of the United States as cited above, consequently making them liable under various federal and state laws.

368. To combat the problem of opioid diversion, the DEA has provided guidance to registrants, including Purdue and its co-conspirators, on the requirements of suspicious order reporting in numerous venues, publications, documents, and final agency actions. Since 2006, the DEA has conducted one-on-one briefings with registrants regarding their downstream customer sales, due diligence responsibilities, and legal and regulatory responsibilities (including the responsibility to know their customers and report suspicious orders to the DEA). The DEA provided registrants with data on controlled substance distribution patterns and trends, including data on the volume of orders, frequency of orders, and percentage of controlled vs. non-controlled purchases. The registrants were given case studies, legal findings against other registrants, and ARCOS profiles of their customers whose previous purchases may have reflected suspicious ordering patterns. The DEA emphasized the “red flags” registrants should look for to identify potential diversion.

369. Since 2007, the DEA has hosted no less than five conferences to provide registrants with updated information about opioid diversion trends. Purdue and its co-conspirators attended at least one of these conferences, which allowed for questions and discussions. The DEA has participated in numerous meetings and events with the legacy Healthcare Distribution Management Association, now the HDA. DEA representatives have provided guidance to the association concerning suspicious order monitoring, and the association has published guidance documents for its members on suspicious order monitoring, reporting requirements, and the diversion of controlled substances.

370. On September 27, 2006, and December 27, 2007, the DEA Office of Diversion Control sent letters to all registrants, including Purdue and its co-conspirators, providing guidance on suspicious order monitoring of controlled substances and the responsibilities and obligations of the registrant to conduct due diligence on controlled substance customers as part of a program to maintain effective controls against diversion.

371. The September 27, 2006, letter reminded registrants that they were required by law to exercise due diligence to avoid filling orders that could be diverted into the illicit market. The DEA explained that as part of the legal obligation to maintain effective controls against diversion, the distributor was required to exercise due care in confirming the legitimacy of each and every order prior to filling. It also described circumstances that could be indicative of diversion including ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs; disproportionate ratio of ordering controlled substances versus non-controlled prescription drugs; the ordering of excessive quantities of a limited variety of controlled substances in combination with lifestyle drugs; and ordering the same controlled substance from multiple distributors. The letter went on to describe what questions should be answered by a registrant when attempting to make a determination if the order is indeed suspicious.

372. On December 27, 2007, the Office of Diversion Control sent a follow-up letter to DEA registrants, including Purdue and its co-conspirators, providing guidance and reinforcing the legal requirements outlined in the September 2006 correspondence. The letter reminded registrants that suspicious orders must be reported when discovered and monthly transaction reports of excessive purchases did not meet the regulatory criteria for suspicious order reporting. The letter also advised registrants that they must perform an independent analysis of a suspicious order prior to the sale to determine if the controlled substances would likely be diverted, and that

filing a suspicious order and then completing the sale does not absolve the registrant from legal responsibility. Finally, the letter directed the registrant community to review a recent DEA action that addressed criteria in determining suspicious orders and their obligation to maintain effective controls against diversion.

373. The HDMA, Purdue and its co-conspirators' own industry group, published Industry Compliance Guidelines titled "Reporting Suspicious Orders and Preventing Diversion of Controlled Substances," emphasizing the critical role of each member of the supply chain in distributing controlled substances.

374. These industry guidelines stated: "At the center of a sophisticated supply chain, distributors are uniquely situated to perform due diligence in order to help support the security of controlled substances they deliver to their customers."

375. Opioid distributors have admitted to the magnitude of the problem and, at least superficially, their legal responsibilities to prevent diversion. They have made statements assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.

376. For example, a Cardinal executive claimed that Cardinal uses "advanced analytics" to monitor its supply chain. He further extolled that Cardinal was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any *outside* criminal activity" (emphasis added).

377. McKesson has publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claimed it is "deeply passionate about curbing the opioid epidemic in our Country."

378. In addition to the obligations imposed by law, through their own words, representations, and actions, Purdue and its co-conspirators have voluntarily undertaken a duty to

protect the public at large against diversion from their supply chains, and to curb the opioid epidemic. In this voluntary undertaking, Purdue and its co-conspirators have miserably and negligently failed.

379. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States. In 2012, Cardinal reached an administrative settlement with the DEA relating to opioid diversion between 2009 and 2012 in multiple states. In December 2016, a Department of Justice press release announced a multi-million dollar settlement with Cardinal for violations of the CSA. In connection with the investigations of Cardinal, the DEA uncovered evidence that Cardinal's own investigator warned Cardinal against selling opioids to certain pharmacies.

380. In May 2008, McKesson entered into a settlement with the DEA on claims that McKesson failed to maintain effective controls against diversion of controlled substances. McKesson allegedly failed to report suspicious orders from rogue Internet pharmacies around the country, resulting in millions of doses of controlled substances being diverted. McKesson agreed to pay a \$13.25 million civil fine. McKesson also was supposed to implement tougher controls regarding opioid diversion. McKesson utterly failed. McKesson's system for detecting "suspicious orders" from pharmacies was so ineffective and dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer. In 2015, McKesson was in the middle of allegations concerning its "suspicious order reporting practices for controlled substances." In early 2017, it was reported that McKesson agreed to pay \$150 million to the government to settle certain opioid diversion claims that it allowed drug diversion at 12 distribution centers in 11 states.

381. In 2007, AmerisourceBergen lost its license to send controlled substances from a distribution center amid allegations that it was not controlling shipments of prescription opioids to Internet pharmacies. Again in 2012, AmerisourceBergen was implicated for failing to protect against diversion of controlled substances into non-medically necessary channels. It has been reported that the U.S. Department of Justice has subpoenaed AmerisourceBergen for documents in connection with a grand jury proceeding seeking information on the company's "program for controlling and monitoring diversion of controlled substances into channels other than for legitimate medical, scientific and industrial purposes."

382. Relying on state laws and regulations, various state boards of pharmacy have directly disciplined the wholesale distributors of prescription opioids for failure to prevent diversion, a duty recognized under state laws and regulations. Although distributors, including Purdue and its co-conspirators, have been penalized by law enforcement authorities, these penalties have not changed their conduct. They pay fines as a cost of doing business in an industry that generates billions of dollars in revenue and profit.

383. Purdue and its co-conspirators have supplied massive quantities of prescription opioids throughout the United States with the actual or constructive knowledge that the opioids were ultimately being consumed for non-medical purposes. Many of these shipments should have been stopped or investigated as suspicious orders, but Purdue and its co-conspirators negligently or intentionally failed to do so.

384. Purdue and its co-conspirators knew or should have known that the amount of opioids that they discharged into the supply chain was far in excess of what could be consumed for medically necessary purposes in the relevant communities (especially given that each co-conspirator knew it was not the only entity servicing those communities).

385. Purdue and its co-conspirators did not adequately control their supply lines to prevent diversion. Manufacturers and distributors of Schedule II controlled substances are required to prevent opioid diversion and protect against it by, for example, taking greater care in hiring, training, and supervising employees; providing greater oversight, security, and control of supply channels; looking more closely at the pharmacists and doctors who were purchasing large quantities of commonly-abused opioids in amounts greater than the populations in those areas would warrant; investigating demographic or epidemiological facts concerning the increasing demand for narcotic painkillers in the United States; providing information to pharmacies and retailers about opioid diversion; and in general, simply following applicable statutes, regulations, professional standards, and guidance from government agencies and using a little bit of common sense.

386. On information and belief, Purdue and its co-conspirators made little to no effort to visit the pharmacies to perform due diligence inspections to ensure that the controlled substances Purdue and its co-conspirators had furnished were not being diverted to illegal uses.

387. On information and belief, the compensation that Purdue and its co-conspirators provided to certain of their employees was affected, in part, by the volume of their sales of opioids, thus improperly creating incentives that contributed to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.

388. It was reasonably foreseeable to Purdue and its co-conspirators that their conduct in flooding the consumer markets of the United States with highly addictive opioids would allow opioids to fall into the hands of women of child-bearing years, as well as women who were already pregnant. Thus, it is reasonably foreseeable to Purdue and its co-conspirators that, when unintended users gain access to opioids, tragic preventable injuries will result, including neonatal

addiction and NAS and a new and substantially different burden of care for the Legal Guardians of the NAS Children.

389. Purdue and its co-conspirators knew or should have known that the opioids being diverted from their supply chains would create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of addiction, demand, illegal transactions, economic ruin, and human tragedy.

390. Purdue and its co-conspirators knew or should have known that a substantial amount of the opioids dispensed in the United States were being dispensed based on invalid or suspicious prescriptions. It was foreseeable that filling suspicious orders for opioids would cause harm to individual Plaintiffs, the putative Class, and the NAS Children for whom they care.

391. Purdue and its co-conspirators were aware of widespread prescription opioid abuse in the United States, but they nevertheless persisted in a pattern of distributing commonly abused and diverted opioids in certain geographic areas—and in such quantities, and with such frequency—that they knew or should have known these commonly abused controlled substances were not being prescribed and consumed for legitimate medical purpose in those areas.

392. Purdue and its co-conspirators could and should have taken action that: (a) limited to 7 days supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed. If Purdue and its co-conspirators had adhered to effective controls to guard against diversion, the Class would have avoided harm.

393. Purdue and its co-conspirators made substantial profits over the years based on the diversion of opioids. Their participation and cooperation in a common enterprise has foreseeably caused damages to Plaintiffs and the Class. Purdue and its co-conspirators knew full well that Plaintiff Legal Guardians and the Class would be unjustly forced to bear these injuries and damages.

394. The Distributor and Pharmacy Purdue and its co-conspirators' intentional distribution of excessive amounts of prescription opioids showed an intentional or reckless disregard for Plaintiff legal Guardians and the Class. Their conduct poses a continuing economic threat to the Legal Guardians who must care for the welfare of the NAS Children.

#### **U. Facts Specific to the RICO Claims**

##### **1. The Opioid Marketing Enterprise**

##### **a. The Common Purpose and Scheme of the Opioid Marketing Enterprise**

395. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Purdue and its RICO Marketing Claim co-conspirators<sup>150</sup> formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

396. In order to unlawfully increase the demand for opioids, Purdue and its RICO Marketing Claim co-conspirators formed an association-in-fact enterprise (the "Opioid Marketing Enterprise") with the "Front Groups" and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and

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<sup>150</sup> Cephalon, Janssen, Endo, and Mallinckrodt.

take actions in furtherance of the Opioid Marketing Enterprise's common purpose. Purdue and its RICO Marketing Claim co-conspirators' substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioids-friendly messaging, fueled the U.S. opioids epidemic.

397. Purdue and its RICO Marketing Claim co-conspirators, through the Opioid Marketing Enterprise, concealed the true risks and dangers of opioids from the medical community and the public, including Plaintiffs, and made misleading statements and misrepresentations about opioids that downplayed the risk of addiction and exaggerated the benefits of opioid use. The misleading statements included: (1) that addiction is rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed; (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an invented condition Purdue and its RICO Marketing Claim co-conspirators named "pseudoaddiction"; (4) that withdrawal is easily managed; (5) that increased dosing present no significant risks; (6) that long-term use of opioids improves function; (7) that the risks of alternative forms of pain treatment are greater than the adverse effects of opioids; (8) that use of time-released dosing prevents addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.

398. The scheme devised, implemented and conducted by Purdue and its RICO Marketing Claim co-conspirators was a common course of conduct designed to ensure that they could unlawfully increase their sales and profits through concealment and misrepresentations about the addictive nature and effective use of their drugs. Purdue and its RICO Marketing Claim co-conspirators, the Front Groups, and the KOLs acted together for a common purpose and perpetuated the Opioid Marketing Enterprise's scheme, including through the unbranded promotion and marketing network as described above.

399. There was regular communication between Purdue and its RICO Marketing Claim co-conspirators, Front Groups and KOLs, in which information was shared, misrepresentations were coordinated, and payments were exchanged. Typically, the coordination, communication and payment occurred, and continues to occur, through the repeated and continuing use of the wires and mail in which Purdue and its RICO Marketing Claim co-conspirators, Front Groups, and KOLs share information regarding overcoming objections and resistance to the use of opioids for chronic pain. Purdue and its RICO Marketing Claim co-conspirators, Front Groups and KOLs functioned as a continuing unit for the purpose of implementing the Opioid Marketing Enterprise's scheme and common purpose, and each agreed and took actions to hide the scheme and continue its existence.

400. At all relevant times, the Front Groups were aware of Purdue and its RICO Marketing Claim co-conspirators' conduct, were knowing and willing participants in and beneficiaries of that conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful fraud, the Front Groups would have had incentive to disclose the deceit by Purdue and its RICO Marketing Claim co-conspirators and the Opioid Marketing Enterprise to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

401. At all relevant times, the KOLs were aware of Purdue and its RICO Marketing Claim co-conspirators' conduct, were knowing and willing participants in that conduct, and reaped benefits from that conduct. Purdue and its RICO Marketing Claim co-conspirators selected KOLs solely because they favored the aggressive treatment of chronic pain with opioids. Purdue and its

RICO Marketing Claim co-conspirators' support helped the KOLs become respected industry experts. And, as they rose to prominence, the KOLs falsely touted the benefits of using opioids to treat chronic pain, repaying Purdue and its RICO Marketing Claim co-conspirators by advancing their marketing goals. The KOLs also knew, but did not disclose, that the other KOLS and Front Groups were engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiffs. But for the Opioid Marketing Enterprise's unlawful conduct, the KOLs would have had incentive to disclose the deceit by Purdue and its RICO Marketing Claim co-conspirators and the Opioid Marketing Enterprise, and to protect their patients and the patients of other physicians. By failing to disclose this information, KOLs furthered the Opioid Marketing Enterprise's scheme and common purpose, and reaped substantial benefits.

402. As public scrutiny and media coverage focused on how opioids ravaged communities throughout the United States, the Front Groups and KOLS did not challenge Purdue and its RICO Marketing Claim co-conspirators' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits and were not supported by medically acceptable evidence.

403. Purdue and its RICO Marketing Claim co-conspirators, Front Groups and KOLS engaged in certain discrete categories of activities in furtherance of the common purpose of the Opioid Marketing Enterprise. As described herein, the Opioid Marketing Enterprise's conduct in furtherance of the common purpose of the Opioid Marketing Enterprise involved: (1) misrepresentations regarding the risk of addiction and safe use of prescription opioids for long-term chronic pain (described in detail above); (2) lobbying to defeat measures to restrict over-

prescription; (3) efforts to criticize or undermine CDC guidelines; and (4) efforts to limit prescriber accountability.

404. In addition to disseminating misrepresentations about the risks and benefits of opioids, the Opioid Marketing Enterprise also furthered its common purpose by criticizing or undermining CDC Guideline. Members of the Opioid Marketing Enterprise criticized or undermined the CDC Guideline, which represented “an important step—and perhaps the first major step from the federal government—toward limiting opioid prescriptions for chronic pain.”

405. Several Front Groups, including the U.S. Pain Foundation and the AAPM, criticized the draft guidelines in 2015, arguing that the “CDC slides presented on Wednesday were not transparent relative to process and failed to disclose the names, affiliation, and conflicts of interest of the individuals who participated in the construction of these guidelines.”

406. The AAPM criticized the prescribing guidelines in 2016, through its immediate past president, stating “that the CDC guideline makes disproportionately strong recommendations based upon a narrowly selected portion of the available clinical evidence.”

407. Purdue and its RICO Marketing Claim co-conspirators alone could not have accomplished the purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and KOLs, who were perceived as “neutral” and more “scientific” than Purdue and its RICO Marketing Claim co-conspirators themselves. Without the work of the Front Groups and KOLs in spreading misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its common purpose.

408. As a result, it is clear that Purdue and its RICO Marketing Claim co-conspirators, the Front Groups, and the KOLs were each willing participants in the Opioid Marketing Enterprise,

had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the enterprise's purpose.

**V. The Conduct of the Opioid Marketing Enterprise Violated Civil RICO**

409. From approximately the late 1990s to the present, each of Purdue and its RICO Marketing Claim co-conspirators exerted control over the Opioid Marketing Enterprise and participated in the operation or management of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. Creating and providing a body of deceptive, misleading and unsupported medical and popular literature about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- b. Creating and providing a body of deceptive, misleading and unsupported electronic and print advertisements about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- c. Creating and providing a body of deceptive, misleading and unsupported sales and promotional training materials about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;

- d. Creating and providing a body of deceptive, misleading and unsupported CMEs and speaker presentations about opioids that (i) understated the risks and overstated the benefits of long-term use; (ii) appeared to be the result of independent, objective research; and (iii) was thus more likely to be relied upon by physicians, patients, and payors;
- e. Selecting, cultivating, promoting and paying KOLs based solely on their willingness to communicate and distribute Purdue and its RICO Marketing Claim co-conspirators' messages about the use of opioids for chronic pain;
- f. Providing substantial opportunities for KOLs to participate in research studies on topics Purdue and its RICO Marketing Claim co-conspirators suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;
- g. Paying KOLs to serve as consultants or on Purdue and its RICO Marketing Claim co-conspirators' advisory boards, on the advisory boards and in leadership positions on Front Groups, and to give talks or present CMEs, typically over meals or at conferences;
- h. Selecting, cultivating, promoting, creating and paying Front Groups based solely on their willingness to communicate and distribute Purdue and its RICO Marketing Claim co-conspirators' messages about the use of opioids for chronic pain;
- i. Providing substantial opportunities for Front Groups to participate in and/or publish research studies on topics Purdue and its RICO Marketing Claim co-

conspirators suggested or chose (and paid for), with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- j. Paying significant amounts of money to the leaders and individuals associated with Front Groups;
- k. Donating to Front Groups to support talks or CMEs, that were typically presented over meals or at conferences;
- l. Disseminating many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;
- m. Sponsoring CME programs put on by Front Groups that focused exclusively on the use of opioids for chronic pain;
- n. Developing and disseminating pro-opioid treatment guidelines with the help of the KOLs as authors and promoters, and the help of the Front Groups as publishers, and supporters;
- o. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by Purdue and its RICO Marketing Claim co-conspirators, such as veterans and the elderly, and then funding that distribution;
- p. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiffs and the public at large; and
- q. Intending that Front Groups and KOLs would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

410. The Opioid Marketing Enterprise had a hierarchical decision-making structure that was headed by Purdue and its RICO Marketing Claim co-conspirators and corroborated by the KOLs and Front Groups. Purdue and its RICO Marketing Claim co-conspirators controlled representations made about their opioids and their drugs, doled out funds to PBMs and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and Purdue and its RICO Marketing Claim co-conspirators' sales detailers were consistent with the Marketing Purdue and its co-conspirators' messaging throughout the United States. The Front Groups and KOLS in the Opioid Marketing Enterprise were dependent on Purdue and its RICO Marketing Claim co-conspirators for their financial structure and for career development and promotion opportunities.

411. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and Purdue and its RICO Marketing Claim co-conspirators' drugs that were consistent with Purdue and its RICO Marketing Claim co-conspirators' messages;
- b. The Front Groups distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;
- c. The Front Groups echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of Purdue and its RICO Marketing Claim co-conspirators;

- d. The Front Groups issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The Front Groups strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The Front Groups concealed their connections to the KOLs and Purdue and its RICO Marketing Claim co-conspirators.

412. Purdue and its RICO Marketing Claim co-conspirators' Front Groups, with their large numbers and credibility with policymakers and the public—have 'extensive influence in specific disease areas. The larger Front Groups likely have a substantial effect on policies relevant to their industry sponsors. By aligning medical culture with industry goals in this way, many of the groups described in this report may have played a significant role in creating the necessary conditions for the U.S. opioid epidemic.

413. The KOLs also participated in the conduct of the affairs of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The KOLs promised to, and did, make representations regarding opioids and Purdue and its RICO Marketing Claim co-conspirators' drugs that were consistent with Purdue and its RICO Marketing Claim co-conspirators' messages themselves;
- b. The KOLs distributed, through the U.S. Mail and interstate wire facilities, promotional and other materials which claimed that opioids could be safely used for chronic pain without addiction, and misrepresented the benefits of using opioids for chronic pain outweighed the risks;

- c. The KOLs echoed and amplified messages favorable to increased opioid use—and ultimately, the financial interests of Purdue and its RICO Marketing Claim co-conspirators;
- d. The KOLs issued guidelines and policies minimizing the risk of opioid addiction and promoting opioids for chronic pain;
- e. The KOLs strongly criticized the 2016 guidelines from the Center for Disease Control and Prevention (CDC) that recommended limits on opioid prescriptions for chronic pain; and
- f. The KOLs concealed their connections to the Front Groups and Purdue and its RICO Marketing Claim co-conspirators, and their sponsorship by Purdue and its RICO Marketing Claim co-conspirators.

414. The scheme devised and implemented by Purdue and its RICO Marketing Claim co-conspirators and members of the Opioid Marketing Enterprise, amounted to a common course of conduct intended to increase Purdue and its RICO Marketing Claim co-conspirators' sales from prescription opioids by encouraging the prescribing and use of opioids for long-term chronic pain. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

**W. Purdue and its RICO Marketing Claim Co-conspirators Controlled and Paid Front Groups and KOLs to Promote and Maximize Opioid Use**

415. As discussed in detail above, Purdue and its RICO Marketing Claim co-conspirators funded and controlled the various Front Groups, including APF, AAPM/APS, FSMB, Alliance for Patient Access, USPF, and AGS. The Front Groups, which appeared to be independent, but were not, transmitted Purdue and its RICO Marketing Claim co-conspirators'

misrepresentations. Purdue and its RICO Marketing Claim co-conspirators and the Front Groups thus worked together to promote the goals of the Opioid Marketing Enterprise.

416. Purdue and its RICO Marketing Claim co-conspirators worked together with each other through the Front Groups that they jointly funded and through which they collaborated on the joint promotional materials described above.

417. Similarly, as discussed in detail above, Purdue and its RICO Marketing Claim co-conspirators paid KOLs, including Drs. Portenoy, Fine, Fishman, and Webster, to spread their misrepresentations and promote their products. Purdue and its RICO Marketing Claim co-conspirators and the KOLs thus worked together to promote the goals of the Opioid Marketing Enterprise.

#### **X. Pattern of Racketeering Activity**

418. Purdue and its RICO Marketing Claim co-conspirators' scheme described herein was perpetrated, in part, through multiple acts of mail fraud and wire fraud, constituting a pattern of racketeering activity as described herein.

419. The pattern of racketeering activity used by Purdue and its RICO Marketing Claim co-conspirators and the Opioid Marketing Enterprise likely involved thousands of separate instances of the use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioid Marketing Enterprise, including essentially uniform misrepresentations, concealments and material omissions regarding the beneficial uses and non-addictive qualities for the long-term treatment of chronic, non-acute and non-cancer pain, with the goal of profiting from increased sales of Purdue and its RICO Marketing Claim co-conspirators' drugs induced by consumers, prescribers, and regulators reliance on Purdue and its RICO Marketing Claim co-conspirators' misrepresentations.

420. Each of these fraudulent mailings and interstate wire transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which Purdue and its RICO Marketing Claim co-conspirators, the Front Groups and the KOLs defrauded and intended to defraud Plaintiffs and the members of the putative class.

421. Purdue and its RICO Marketing Claim co-conspirators devised and knowingly carried out an illegal scheme and artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts regarding the safe, non-addictive and effective use of opioids for long-term chronic, non-acute and non-cancer pain. Purdue and its RICO Marketing Claim co-conspirators and members of the Opioid Marketing Enterprise knew that these representations violated the FDA approved use these drugs, and were not supported by actual evidence. Purdue and its RICO Marketing Claim co-conspirators intended that that their common purpose and scheme to defraud would, and did, use the U.S. Mail and interstate wire facilities, intentionally and knowingly with the specific intent to advance, and for the purpose of executing, their illegal scheme.

422. By intentionally concealing the material risks and affirmatively misrepresenting the benefits of using opioids for chronic pain to prescribers, regulators, and pregnant women and women of child-bearing years, including Plaintiffs, Purdue and its RICO Marketing Claim co-conspirators, the Front Groups, and the KOLs engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

423. Purdue and its RICO Marketing Claim co-conspirators' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, publications, representations, statements, electronic transmissions, payments, including, *inter alia*:

- a. Marketing materials about opioids, and their risks and benefits, which Purdue and its RICO Marketing Claim co-conspirators sent to health care providers, transmitted through the internet and television, published, and transmitted to Front Groups and KOLs located across the country;
- b. Written representations and telephone calls between Purdue and its RICO Marketing Claim co-conspirators and Front Groups regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- c. Written representations and telephone calls between Purdue and its RICO Marketing Claim co-conspirators and KOLs regarding the misrepresentations, marketing statements and claims about opioids, including the non-addictive, safe use of chronic long-term pain generally;
- d. E-mails, telephone and written communications between Purdue and its RICO Marketing Claim co-conspirators and the Front Groups agreeing to or implementing the opioids marketing scheme;
- e. E-mails, telephone and written communications between Purdue and its RICO Marketing Claim co-conspirators and the KOLs agreeing to or implementing the opioids marketing scheme;
- f. Communications between Purdue and its RICO Marketing Claim co-conspirators, Front Groups and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;

- g. Communications between Purdue and its RICO Marketing Claim co-conspirators, KOLs and the media regarding publication, drafting of treatment guidelines, and the dissemination of the same as part of the Opioid Marketing Enterprise;
- h. Written and oral communications directed to State and Federal agencies, federal and state courts, and private insurers that fraudulently misrepresented the risks and benefits of using opioids for chronic pain; and
- i. Receipts of increased profits sent through the U.S. Mail and interstate wire facilities—the wrongful proceeds of the scheme.

424. In addition to the above-referenced predicate acts, it was intended by and foreseeable to Purdue and its RICO Marketing Claim co-conspirators that the Front Groups and the KOLs would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

425. To achieve the common goal and purpose of the Opioid Marketing Enterprise, Purdue and its RICO Marketing Claim co-conspirators and members of the Opioid Marketing Enterprise hid from the consumers, prescribers, regulators and the Plaintiffs: (a) the fraudulent nature of the RICO Marketing Purdue and its co-conspirators' marketing scheme; (b) the fraudulent nature of statements made by Purdue and its RICO Marketing Claim co-conspirators and by their KOLs, Front Groups and other third parties regarding the safety and efficacy of prescription opioids; and (c) the true nature of the relationship between the members of the Opioid Marketing Enterprise.

426. Purdue and its RICO Marketing Claim co-conspirators, and each member of the Opioid Marketing Enterprise agreed, with knowledge and intent, to the overall objective of Purdue and its RICO Marketing Claim co-conspirators' fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in marketing prescription opioids.

427. Indeed, for Purdue and its RICO Marketing Claim co-conspirators' fraudulent scheme to work, each of them had to agree to implement similar tactics regarding fraudulent marketing of prescription opioids. This conclusion is supported by the fact that Purdue and its RICO Marketing Claim co-conspirators each financed, supported, and worked through the same KOLs and Front Groups, and often collaborated on and mutually supported the same publications, CMEs, presentations, and prescription guidelines

428. Purdue and its RICO Marketing Claim co-conspirators' predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs, the putative class, and the NAS Children, while simultaneously generating billion-dollar revenue and profits for Purdue and its RICO Marketing Claim co-conspirators. The predicate acts were committed or caused to be committed by Purdue and its RICO Marketing Claim co-conspirators through their participation in the Opioid Marketing Enterprise and in furtherance of its fraudulent scheme.

### **1. The Opioid Supply Chain Enterprise**

429. Faced with the reality that they will now be held accountable for the consequences of the opioid epidemic they created, members of the industry resorted to "a categorical denial of any criminal behavior or intent."<sup>151</sup> Purdue and its RICO Supply Chain Claim co-conspirators'<sup>152</sup>

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<sup>151</sup> McKesson Responds to Recent 60 Minutes Story About January 2017 Settlement With the Federal Government, McKesson, <http://www.mckesson.com/about-mckesson/fighting-opioidabuse/60-minutes-response> (last visited Apr. 21, 2018).

<sup>152</sup> Cephalon, Endo, Mallinckrodt, Actavis, McKesson, AmerisourceBergen, and Cardinal.

actions went far beyond what could be considered ordinary business conduct. For more than a decade, certain Purdue and its co-conspirators worked together in an illicit enterprise, engaging in conduct that was not only illegal, but in certain respects anti-competitive, with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict.

430. Knowing that dangerous drugs have a limited place in our society, and that their dissemination and use must be vigilantly monitored and policed to prevent the harm that drug abuse and addiction causes to individuals, society and governments, Congress enacted the Controlled Substances Act (“CSA”). Specifically, through the CSA, which created a closed system of distribution for controlled substances, Congress established an enterprise for good. CSA imposes a reporting duty that cuts across company lines. Regulations adopted under the CSA require that companies who are entrusted with permission to operate within this system cannot simply operate in an “anything goes” profit-maximizing market. Instead, the statute tasks them to watch over each other with a careful eye for suspicious activity. Driven by greed, Purdue and its co-conspirators betrayed that trust and subverted the constraints of the CSA’s closed system to conduct their own enterprise for evil.

431. As “registrants” under the CSA, Purdue and its RICO Supply Chain Claim co-conspirators are duty bound to identify and report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>153</sup> Critically, Purdue and its co-conspirators’ responsibilities do not end with the products they manufacture or distribute—there is no such limitation in the law because their duties cut across company lines. Thus, when Purdue and its co-conspirators obtain information about the sales and distribution of other

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<sup>153</sup> 21 C.F.R. § 1301.74(b).

companies' opioid products, as they did through data mining companies like IMS Health, they were legally obligated to report that activity to the DEA.

432. If morality and the law did not suffice, competition dictates that Purdue and its co-conspirators would turn in their rivals when they had reason to suspect suspicious activity. Indeed, if a manufacturer or distributor could gain market share by reporting a competitor's illegal behavior (causing it to lose a license to operate, or otherwise inhibit its activity), ordinary business conduct dictates that it would do so. Under the CSA this whistleblower or watchdog function is not only a protected choice, but a statutory mandate. Unfortunately, however, that is not what happened. Instead, knowing that investigations into potential diversion would only lead to shrinking markets, Purdue and its RICO Supply Chain Claim co-conspirators elected to operate in a conspiracy of silence, in violation of both the CSA and RICO.

433. Purdue and its RICO Supply Chain Claim co-conspirators' scheme required the participation of all. If any one member broke rank, its compliance activities would highlight deficiencies of the others, and the artificially high quotas they maintained through their scheme would crumble. But, if all the members of the enterprise conducted themselves in the same manner, it would be difficult for the DEA to go after any one of them. Accordingly, through the connections they made as a result of their participation in the Healthcare Distribution Alliance ("HDA"), Purdue and its RICO Supply Chain Claim co-conspirators chose to flout the closed system designed to protect the Plaintiffs, the putative class, and the NAS Children. Publicly, in 2008, Purdue and its RICO Supply Chain Claim co-conspirators announced their formulation of "Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention Diversion of Controlled Substances." But, privately, Purdue and its RICO Supply Chain Claim co-conspirators refused to act and through their lobbying efforts, they collectively sought to undermine the impact

of the CSA. Indeed, despite the issuance of these Industry Compliance Guidelines, which recognize Purdue and its co-conspirators' duties under the law, as illustrated by the subsequent industry-wide enforcement actions and consent orders issued after that time, none of them complied. John Gray, President and CEO of the HDA said to Congress in 2014, it is "difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications." Yet, Purdue and its RICO Supply Chain Claim co-conspirators apparently all found the same profit-maximizing balance—intentionally remaining silent to ensure the largest possible financial return.

434. As described above, at all relevant times, Purdue and its RICO Supply Chain Claim co-conspirators operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by fraudulently increasing the quotas set by the DEA that would allow them to collectively benefit from a greater pool of prescription opioids to manufacture and distribute. In support of this common purpose and fraudulent scheme, Purdue and its RICO Supply Chain Claim co-conspirators jointly agreed to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market so that those orders would not result in a decrease, or prevent an increase in, the necessary quotas.

435. At all relevant times, as described above, Purdue and its RICO Supply Chain Claim co-conspirators exerted control over, conducted and/or participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were complying with their duties under the CSA to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, and to halt such unlawful sales, so as to increase production quotas and generate unlawful profits, as follows:

436. Purdue and its RICO Supply Chain Claim co-conspirators disseminated false and misleading statements to state and federal regulators claiming that:

- a. the quotas for prescription opioids should be increased;
- b. they were complying with their obligations to maintain effective controls against diversion of their prescription opioids;
- c. they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids;
- d. they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids; and
- e. they did not have the capability to identify suspicious orders of controlled substances.

437. Purdue and its co-conspirators applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the “Ensuring Patient Access and Effective Drug Enforcement Act.”<sup>154</sup>

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<sup>154</sup> *HDMA is Now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, <http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distributionalliance/> (last updated July 6, 2016); Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post (Oct. 22, 2016), [https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9\\_story.html](https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13-d7c704ef9fd9_story.html); Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post (Mar. 6, 2017), [https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-deaenforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf\\_story.html](https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-deaenforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html); Eric Eyre, *DEA Agent: “We Had no Leadership” in WV Amid Flood of Pain Pills*, Charleston GazetteMail (Feb. 18, 2017), <http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-noleadership-in-wv-amid-flood-of-pain-pills->.

438. The CSA and the Code of Federal Regulations, require Purdue and its RICO Supply Chain Claim co-conspirators to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders. The failure to make reports as required by the CSA and Code of Federal Regulations amounts to a criminal violation of the statute.

439. Purdue and its RICO Supply Chain Claim co-conspirators knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA including the Marketing Purdue and its co-conspirators' applications for production quotas. Specifically, Purdue and its RICO Supply Chain Claim co-conspirators were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

440. Purdue and its RICO Supply Chain Claim co-conspirators used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

441. In devising and executing the illegal scheme, Purdue and its RICO Supply Chain Claim co-conspirators devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

442. For the purpose of executing the illegal scheme, Purdue and its RICO Supply Chain Claim co-conspirators committed racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme. These racketeering acts, which included repeated acts of mail fraud and wire fraud, constituted a pattern of racketeering.

443. Purdue and its RICO Supply Chain Claim co-conspirators' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Marketing Purdue and its co-conspirators, Purdue and its co-conspirators, or third parties that were foreseeably caused to be sent as a result of Purdue and its RICO Supply Chain Claim co-conspirators' illegal scheme, including but not limited to:

- a. The prescription opioids themselves;
- b. Documents and communications that supported and/or facilitated Purdue and its RICO Supply Chain Claim co-conspirators' request for higher aggregate production quotas, individual production quotas, and procurement quotas;
- c. Documents and communications that facilitated the manufacture, purchase and sale of prescription opioids;
- d. RICO Supply Chain Purdue and its co-conspirators' DEA registrations;
- e. Documents and communications that supported and/or facilitated RICO Supply Chain Purdue and its co-conspirators' DEA registrations;
- f. RICO Supply Chain Purdue and its co-conspirators' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827;
- g. Documents and communications related to the RICO Supply Chain Purdue and its co-conspirators' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

- h. Documents intended to facilitate the manufacture and distribution of Purdue and its RICO Supply Chain Claim co-conspirators' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence;
- i. Documents for processing and receiving payment for prescription opioids;
- j. Payments from the Distributors to the Marketing Purdue and its co-conspirators;
- k. Rebates and chargebacks from the Marketing Purdue and its co-conspirators to the Distributors Purdue and its co-conspirators;
- l. Payments to Purdue and its RICO Supply Chain Claim co-conspirators' lobbyists through the PCF;
- m. Payments to Purdue and its RICO Supply Chain Claim co-conspirators' trade organizations, like the HDA, for memberships and/or sponsorships;
- n. Deposits of proceeds from Purdue and its RICO Supply Chain Claim co-conspirators' manufacture and distribution of prescription opioids; and
- o. Other documents and things, including electronic communications.

444. Purdue and its RICO Supply Chain Claim co-conspirators (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule

<b>Purdue</b>	(1) Purdue Pharma, LP,	OxyContin	Oxycodone hydrochloride extended release	Schedule II
	(2) Purdue Pharma, Inc.,	MS Contin	Morphine sulfate extended release	Schedule II
	(3) The Purdue Frederick Company	Dilaudid	Hydromorphone hydrochloride	Schedule II
		Dilaudid-HP Dilaudid-HP	Hydromorphone hydrochloride	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
		Butrans	Buprenorphine	Schedule II
		Hysinga ER	Hydrocodone bitrate	Schedule II
		Targiniq ER	Oxycodone hydrochloride	Schedule II
<b>Cephalon</b>	(1) Cephalon, Inc.,	Actiq	Fentanyl citrate	Schedule II
	(2) Teva Pharmaceutical Industries, Ltd.,	Fentora	Fentanyl citrate	Schedule II
	(3) Teva Pharmaceuticals USA, Inc.	Generic oxycodone	Oxycodone hydrochloride	Schedule II
<b>Endo</b>	(1) Endo Health Solutions, Inc.,	Opana ER	Oxymorphone hydrochloride extended release	Schedule II
	(2) Endo Pharmaceuticals Inc.,	Opana	Oxymorphone hydrochloride	Schedule II
	(3) Qualitest Pharmaceuticals, Inc. ( <i>wholly-owned subsidiary of Endo</i> )	Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
		Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II

		Generic oxycodone		Schedule II
		Generic oxymorphone		Schedule II
		Generic hydromorphone		Schedule II
		Generic hydrocodone		Schedule II
<b>Mallinckrodt</b>	(1) Mallinckrodt plc,	Exalgo	Hydromorphone hydrochloride	Schedule II
	(2) Mallinckrodt LLC ( <i>wholly-owned subsidiary of Mallinckrodt plc</i> )	Roxicodone	Oxycodone hydrochloride	Schedule II
<b>Actavis</b>	(1) Allergan Plc,	Kadian	Morphine Sulfate	Schedule II
	(2) Actavis LLC, (3) Actavis Pharma, Inc., (4) Actavis Plc,	Norco (Generic of Kadian)	Hydrocodone and acetaminophen	Schedule II

Defendant Group Name	Company Names	Drugs		
		Drug Name	Chemical Name	CSA Schedule
	(5) Actavis, Inc.,			
	(6) Watson Pharmaceuticals, Inc., Watson Pharma, Inc.	Generic Duragesic	Fentanyl	Schedule II
		Generic Opana	Oxymorphone hydrochloride	Schedule II

445. Each of Purdue and its RICO Supply Chain Claim co-conspirators identified manufactured, shipped, paid for and received payment for the drugs identified above, throughout the United States.

446. Purdue and its RICO Supply Chain Claim co-conspirators used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, Purdue and its RICO Supply Chain Claim co-conspirators made misrepresentations

about their compliance with Federal and State laws requiring them to identify, investigate and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

447. At the same time, Purdue and its RICO Supply Chain Claim co-conspirators misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids.

448. Purdue and its RICO Supply Chain Claim co-conspirators utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales, and to transmit payments and rebates/chargebacks.

449. Purdue and its RICO Supply Chain Claim co-conspirators also communicated by U.S. Mail, by interstate facsimile, and by interstate electronic mail with each other and with various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

450. The mail and wire transmissions described herein were made in furtherance of the RICO Supply Chain Purdue and its co-conspirators' scheme and common course of conduct to deceive regulators, the public and the Plaintiffs that these Purdue and its co-conspirators were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids all while Purdue and its co-conspirators were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. Purdue and its RICO Supply Chain Claim co-conspirators' scheme and common course of conduct was to increase or maintain high production quotas for their prescription opioids from which they could profit.

451. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden by Purdue and its co-conspirators and cannot be alleged without access to Purdue and its co-conspirators' books and records. However, Plaintiffs have described the types of, and in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

452. Purdue and its RICO Supply Chain Claim co-conspirators did not undertake the practices described herein in isolation, but as part of a common scheme. Various other persons, firms, and corporations, including third-party entities and individuals not named as Purdue and its co-conspirators in this Complaint, may have contributed to and/or participated in the scheme with these Purdue and its co-conspirators in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for Purdue and its RICO Supply Chain Claim co-conspirators.

453. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

454. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating billions of dollars in revenue and profits for Purdue and its RICO Supply Chain Claim co-conspirators. The predicate acts were committed or caused to be committed by Purdue and its co-conspirators through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

455. As described above, Purdue and its RICO Supply Chain Claim co-conspirators were repeatedly warned, fined, and found to be in violation of applicable law and regulations, and yet they persisted. The sheer volume of enforcement actions against Purdue and its RICO Supply Chain Claim co-conspirators supports this conclusion that Purdue and its RICO Supply Chain Claim co-conspirators operated through a pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.

456. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting Plaintiffs, the putative class members, and the NAS Children. Purdue and its RICO Supply Chain Claim co-conspirators calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have. Purdue and its RICO Supply Chain Claim co-conspirators were aware that Plaintiffs the putative class members, and the NAS Children relied on Purdue and its co-conspirators to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

457. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Purdue and its RICO Supply Chain Claim co-conspirators engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

## **VI. DISCOVERY RULE AND TOLLING**

458. Debtor Defendant Purdue and its co-conspirators' conduct was well-concealed, and only recently uncovered through exhaustive investigation and research. Purdue and its co-conspirators deliberately conducted much of their deception through in-person meetings and conferences in order to avoid generating a potentially discoverable paper trail of their misconduct.

Purdue and its co-conspirators also concealed from the general public their internal communications about their deceptive course of conduct, including their plans to cause more patients to take higher doses for longer periods and, separately, their knowledge of inappropriate practices of prescribing by so-called “high-prescribing doctors” that they had targeted to prescribe their opioids.

459. Discovering the nature and extent of Purdue and its co-conspirators’ conduct has been a time-consuming and complex process, further strained by their failure to document their activities when they were legally required to do so, failure to comply with required reporting standards, lack of cooperation, and baseless denials.

460. Furthermore, Plaintiffs allege on behalf of themselves and the putative class ongoing torts, as well as ongoing duties of care to the minor NAS Children.

461. Any statutes of limitation otherwise applicable to any claims asserted herein against Debtor Purdue and all named entities have been tolled by the discovery rule, rules regarding fraudulent concealment, and/or the fact that the torts alleged are ongoing and the NAS Guardian’s duties of care for minor children are also ongoing.

## **VII. CLASS ACTION ALLEGATIONS**

### **A. The Class Definitions**

462. The Legal Guardian Putative Classes are defined as:<sup>155</sup>

- a. Class 1: Legal Guardians<sup>156</sup> of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence

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<sup>155</sup> The definitions of terms for Class 1 and Class 2 shall also apply to those same identical terms in the definitions for Classes 2-4 and are not repeated again for purposes of brevity.

<sup>156</sup> The term “Legal Guardian” is defined for purposes of this putative class action as “any natural person or entity who has the primary legal responsibility under their respective laws of their state

Syndrome” (“NAS”)<sup>157</sup> at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured and/or distributed by Purdue.<sup>158</sup>

- b. Class 2: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates prior to the birth and those opioids or opiates were manufactured and/or distributed by one or more of Purdue’s RICO Marketing Claim or RICO Supply Chain Claim co-conspirators.<sup>159</sup>
- c. Class 3: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates in the ten months prior to the birth and those opioids or opiates were manufactured and/or distributed by Purdue.
- d. Class 4: Legal Guardians of United States residents born after May 25, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence

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for an infant or child’s physical, mental, and emotional development.” Expressly excluded from the class of “Legal Guardians” are any governmental entities.

“Legal Guardians” include natural and adoptive parents who have not otherwise lost legal custody of their children, legal custodians, legal caretakers, and court-appointed guardians (including guardians of the person), whether temporary or permanent.

<sup>157</sup> The term “NAS” is defined to include additional, but medically-symptomatic identical, terminology and diagnostic criteria, including Neonatal Opioid Withdrawal Syndrome (NOWS) and other historically and regionally used medical and/or hospital diagnostic criteria for infants born addicted to opioids. Additional specifics on these readily identifiable and ascertainable terms will be provided in Plaintiffs’ Motion for Class Certification.

<sup>158</sup> Defined in the “Parties” sections, *infra*, at § II. B. i.

<sup>159</sup> Defined in the “Parties” sections, *infra*, at § II. B. ii., and iii.

Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates in the ten months prior to the birth and those opioids or opiates were manufactured and/or distributed by one or more of Purdue’s RICO Marketing Claim or RICO Supply Chain Claim co-conspirators.

463. Expressly excluded from the Classes are any infants or children who were treated with opioids neonatally, other than for pharmacological weaning. Also excluded from the class are Legal Guardianships where a governmental agency, such as a public children services agency, has affirmatively assumed the duties of “custodian” of the child.<sup>160</sup>

**B. Certification under Federal Rules of Bankruptcy Procedure Rule 7023, Fed.R.Civ. P. 23 (a) and Fed.R. Civ. 23 (b)**

**1. FRCP 23(a) and General Class Allegations**

464. The class is so numerous that joinder of all members is impracticable.

465. There are questions of law or fact common to the class, which are set out below.

466. The claims and defenses of the representative parties are typical of the claims or defenses of the class.

467. The representatives will fairly and adequately protect the interests of the class.

468. The members of each class are readily identifiable from medical records, state and federal registries, and pharmacy records. As a result, the determination of membership in the class is a simple, mechanical process.

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<sup>160</sup> There are only two causes of NAS: (1) *in utero* exposure to opioids *via* the birth mother, and (2) post-birth treatment of the infant with opioids for pain. The latter category does not include pharmacological weaning for dependency, as those infants are necessarily part of the former category, i.e., infants who were exposed *in utero* and then treated with opioids pursuant to a weaning protocol of gradually tapering doses. Whether a newborn or an infant was treated with opioids for pain can be determined from medical records. Any such children are necessarily excluded from the class definition.

469. Upon information and belief, the members of each class consist of thousands of members and is so numerous that individual joinder of all members is impracticable. The members of the class are geographically dispersed throughout the United States.

470. Plaintiffs will fairly and adequately protect the interests of the members of the class. Plaintiffs have retained counsel who are highly experienced and competent in class-action litigation, and Plaintiffs and their counsel intend to prosecute this action vigorously. Neither Plaintiffs nor their counsel have any interests that might cause them not to vigorously pursue this action. Plaintiffs' interests are coextensive with those of the class, and Plaintiffs have no interests adverse to those of the class members.

471. Plaintiffs have made arrangements with counsel for the discharge of their financial responsibilities to the class. Plaintiffs' counsel has the necessary financial resources to adequately and vigorously litigate this class action.

## **2. Certification under FRCP 23(b)(2)**

472. Certification is appropriate under FED. R. CIV. P. 23(b)(2). The party expected to oppose the Class, the Defendant Debtor Purdue, has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief, i.e., the abatement, is appropriate respecting the class as a whole.

473. The requested abatement relief is viable only on a class-wide, non-individual basis. Efficacious relief requires that *all* similarly situated NAS Children and their Guardians be enrolled in a comprehensive and uniform monitoring and surveillance plan with the class-wide resulting data driven into the supervisory Science Panel so that it may study and inform itself according to scientific and medical principals which require robust data sets and then make care

recommendations as a result. There can be no Science Panel convened for a single NAS Child, and certainly no epidemiological studies from a data set of “1.”

**3. Alternative Certification under FRCP 23(b)(1)**

474. Alternatively, and only if the Court finds that there is not a sufficient basis for FED. R. Civ. P. 23(b)(2) certification, Plaintiffs request alternative certification under 23(b)(1). Prosecuting separate abatement actions by individual class members is especially fraught, if not impossible, due to the unique nature of the relief sought which requires the participation of all Legal Guardians of the NAS Children.

475. Further, this bankruptcy proceeding involves a limited fund which has significant implications on the abilities of the Plaintiffs and the putative class members to protect their legal interests and prosecute their claims against Defendant Debtor Purdue.

476. Adjudications with respect to individual class members would, as a practical matter, be dispositive of the interests of the other members not a party to those individual adjudications and/or would substantially impair or impede their ability to protect their interests. Certification under Fed.R.Civ.P. 23(b)(1)(B) is appropriate.

477. Alternatively, certification under Fed.R.Civ.P. 23(b)(1)(A) is appropriate as there is the possibility of inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the motion.

**4. Alternative Certification under Fed. R. Civ. P. 23(b)(3)**

478. Alternatively, and only if the Court finds that there is not a sufficient basis for FED. R. Civ. P. 23(b)(2) or (b)(1), certification, Plaintiffs request alternative certification under FED. R. Civ. P. 23(b)(3).

479. There are questions of law and fact common to the class, which predominate over any questions affecting only individual members of a class. The wrongs suffered and remedies sought by Plaintiffs and the other members of the class are premised upon a uniform unlawful scheme perpetuated by Purdue and its co-conspirators. Plaintiffs have pled a claim for compensatory relief only in the alternative. Should Plaintiffs move for class certification with a request for compensatory relief, the sole question that might affect individual members of the class is the exact monetary recovery of past medical expenses for the NAS Children for which the Legal Guardians were responsible. This recovery is both incidental and nearly insignificant as compared to the injunctive relief sought.

480. Predominating questions common to the class include, but are not limited to, the following:

- a. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators fail to monitor, detect, investigate, refuse to fill, and/or report suspicious orders of prescription opioids?
- b. Did the Debtor Defendant Purdue separately, and/or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators fail to monitor, detect, investigate, refuse to fill, and/or report orders of prescription opioids which they knew or should have known were likely to be diverted for nonmedical purposes?
- c. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim co-conspirators use false statements and omissions to promote and market opioids for treatment of chronic pain?

- d. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim co-conspirators use false statements and omissions to promote and market opioids for treatment of non-cancer, including but not limited to widespread conditions such as arthritis and joint pain?
- e. Did the Debtor Defendant Purdue separately and or in concert with the RICO Marketing Claim co-conspirators use false statements and omissions to promote and market opioids as drugs without dose limits?
- f. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim co-conspirators make false statements and omit relevant facts to better promote and market opioids by misrepresenting the risks and benefits of prescribing and/or taking opioids?
- g. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim co-conspirators, negligently manufacture, market, promote, and sell opioids?
- h. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators negligently sell and distribute opioids?
- i. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators, recklessly, or with gross negligence manufacture, market, promote, and sell opioids?
- j. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators wantonly, recklessly, or with gross negligence manufacture, sell and/or distribute opioids?

- k. Did the Debtor Defendant Purdue separately and/or in concert with the RICO Marketing Claim co-conspirators manufacture and cause to be marketed opioids which it knew were being prescribed to pregnant women without adequately testing and/or issuing adequate warnings concerning the short-term and long-term risks to the fetus?
- l. Were Plaintiffs and the class members damaged as a direct and proximate result of Debtor Defendant Purdue's acts and omissions either separately or in concert with the RICO Marketing Claim and RICO Supply Chain Claim co-conspirators' acts and omissions?
- m. Are Plaintiffs' claims typical of those of the class and are based on the same legal theories as those of the class members?
- n. Do Plaintiffs' claims and those of the class members all arise from the same pattern or practice by Debtor Defendant Purdue acting separately, and/or in concert with RICO Marketing Claim and RICO Supply Chain Claim co-conspirators?

481. Furthermore, a class action is superior to all other available means for the fair and efficient adjudication of this controversy. It is desirable to concentrate the litigation of the claims in this forum and for relief to proceed on a classwide basis. Indeed, the requested abatement relief is viable only on a class-wide, non-individual basis. Efficacious relief requires that *all* similarly situated NAS Children and their Guardians be enrolled in a comprehensive and uniform monitoring and surveillance plan with the class-wide resulting data driven into the supervisory Science Panel so that it may study and inform itself according to scientific and medical principals which require robust data sets and then make care recommendations as a result. There can be no

Science Panel convened for a single NAS Child, and certainly no epidemiological studies from a data set of “1.”

482. Further, it is unlikely that the class members, on an individual basis, could obtain effective redress for the specific harms made the subject of this complaint (and indeed, relief for that harm can come only through the class-wide abatement). Additionally, the court system would be adversely affected by such individualized litigation. Individualized litigation would create the danger of inconsistent or contradictory attempted abatements arising from the same set of facts. Individualized litigation would also increase delay and expense to all parties and the court system from the issues raised by this action. In contrast, the class-action device provides the benefit of adjudication of these issues in a single proceeding, with economies of scale and comprehensive supervision by a single court.

**C. Interim Appointment of Class Counsel under Fed. R. Civ. P. 23(g)(2)**

483. Interim appointment of class counsel to represent the putative class in prosecuting this action is warranted and is necessary to defend against expected objections and to manage precertification matters on behalf of the putative class.

**VIII. CLAIMS FOR RELIEF**

**A. Claim 1: Violation of RICO, 18 U.S.C. § 1961 et seq.—Opioid Marketing Enterprise**

484. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

485. Purdue and its RICO Marketing Claim co-conspirators<sup>161</sup> through the use of “Front Groups” that appeared to be independent of Purdue and its RICO Marketing Claim co-conspirators; through the dissemination of publications that supported Purdue and its RICO

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<sup>161</sup> Cephalon, Janssen, Endo, and Mallinckrodt.

Marketing Claim co-conspirators' scheme; through continuing medical education ("CME") programs controlled and/or funded by Purdue and its RICO Marketing Claim co-conspirators; by the hiring and deployment of so-called "key opinion leaders," ("KOLs") who were paid by Purdue and its RICO Marketing Claim co-conspirators to promote their message; and through the "detailing" activities of Purdue and its RICO Marketing Claim co-conspirators' sales forces—conducted an association-in-fact enterprise, and/or participated in the conduct of an enterprise through a pattern of illegal activities (the predicate racketeering acts of mail and wire fraud) to carry-out the common purpose of the Opioid Marketing Enterprise, *i.e.*, to unlawfully increase profits and revenues from the continued prescription and use of opioids for long-term chronic pain. Through the racketeering activities of the Opioid Marketing Enterprise sought to further the common purpose of the enterprise through a fraudulent scheme to change prescriber habits and public perception about the safety and efficacy of opioid use by convincing them that each of the nine false propositions alleged earlier were true. In so doing, each of Purdue and its RICO Marketing Claim co-conspirators knowingly conducted and participated in the conduct of the Opioid Marketing Activities by engaging in mail and wire fraud in violation of 18 U.S.C. §§ 1962(c) and (d).

486. The Opioid Marketing Enterprise alleged above, is an association-in-fact enterprise that consists of Purdue and its RICO Marketing Claim co-conspirators (Purdue, Cephalon, Janssen, Endo, and Mallinckrodt); the Front Groups (APF, AAPM, APS, FSMB, USPF, and AGS); and the KOLs (Dr. Portenoy, Dr. Webster, Dr. Fine, and Dr. Fishman).

487. Each of Purdue and its RICO Marketing Claim co-conspirators and the other members of the Opioid Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing Enterprise by playing a distinct role in furthering the enterprise's common

purpose of increasing profits and sales through the knowing and intentional dissemination of false and misleading information about the safety and efficacy of long-term opioid use, and the risks and symptoms of addiction, in order increase the market for prescription opioids by changing prescriber habits and public perceptions and increase the market for opioids.

488. Specifically, Purdue and its RICO Marketing Claim co-conspirators each worked together to coordinate the enterprise's goals and conceal their role, and the enterprise's existence, from the public by, among other things, (i) funding, editing and distributing publications that supported and advanced their false messages; (ii) funding KOLs to further promote their false messages; (iii) funding, editing and distributing CME programs to advance their false messages; and (iv) tasking their own employees to direct deceptive marketing materials and pitches directly at physicians and, in particular, at physicians lacking the expertise of pain care specialists (a practice known as sales detailing).

489. Each of the Front Groups helped disguise the role of RICO Marketing Purdue and its co-conspirators by purporting to be unbiased, independent patient-advocacy and professional organizations in order to disseminate patient education materials, a body of biased and unsupported scientific "literature," and "treatment guidelines" that promoted Purdue and its RICO Marketing Claim co-conspirators false messages.

490. Each of the KOLs were physicians chosen and paid by each of Purdue and its RICO Marketing Claim co-conspirators to influence their peers' medical practice by promoting the Marketing Defendant's false message through, among other things, writing favorable journal articles and delivering supportive CMEs as if they were independent medical professionals, thereby further obscuring Purdue and its RICO Marketing Claim co-conspirators' role in the enterprise and the enterprise's existence.

491. Further, each of Purdue and its RICO Marketing Claim co-conspirators, KOLs and Front Groups that made-up the Opioid Marketing Enterprise had systematic links to and personal relationships with each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The systematic links and personal relationships that were formed and developed allowed members of the Opioid Marketing Enterprise the opportunity to form the common purpose and agree to conduct and participate in the conduct of the Opioid Marketing Enterprise. Specifically, each of Purdue and its RICO Marketing Claim co-conspirators coordinated their efforts through the same KOLs and Front Groups, based on their agreement and understanding that the Front Groups and KOLs were industry friendly and would work together with Purdue and its RICO Marketing Claim co-conspirators to advance the common purpose of the Opioid Marketing Enterprise; each of the individuals and entities who formed the Opioid Marketing Enterprise acted to enable the common purpose and fraudulent scheme of the Opioid Marketing Enterprise.

492. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence separate and distinct from each RICO Marketing Defendant and its members; (b) was separate and distinct from the pattern of racketeering in which Purdue and its RICO Marketing Claim co-conspirators engaged; (c) was an ongoing and continuing organization consisting of individuals, persons, and legal entities, including each of Purdue and its RICO Marketing Claim co-conspirators; (d) was characterized by interpersonal relationships between and among each member of the Opioid Marketing Enterprise, including between Purdue and its RICO Marketing Claim co-conspirators and each of the Front Groups and KOLs; (e) had sufficient longevity for the enterprise to pursue its purpose and functioned as a continuing unit.

493. The persons and entities engaged in the Opioid Marketing Enterprise are systematically linked through contractual relationships, financial ties, personal relationships, and continuing coordination of activities, as spearheaded by Purdue and its RICO Marketing Claim co-conspirators.

494. Purdue and its RICO Marketing Claim co-conspirators conducted and participated in the conduct of the Opioid Marketing Enterprise through a pattern of racketeering activity that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by changing prescriber habits and public perceptions in order to increase the prescription and use of prescription opioids, and expand the market for opioids.

495. Purdue and its RICO Marketing Claim co-conspirators each committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that Purdue and its RICO Marketing Claim co-conspirators committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by Purdue and its RICO Marketing Claim co-conspirators’ regular use of the facilities, services, distribution channels, and employees of the Opioid Marketing Enterprise, the U.S. Mail and interstate wire facilities. Purdue and its RICO Marketing Claim co-conspirators participated in the scheme to defraud by using mail, telephones and the Internet to transmit mailings and wires in interstate or foreign commerce.

496. Purdue and its RICO Marketing Claim co-conspirators’ predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: Purdue and its RICO Marketing Claim co-conspirators violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: Purdue and its RICO Marketing Claim co-conspirators violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.

497. Indeed, as summarized herein, Purdue and its RICO Marketing Claim co-conspirators used the mail and wires to send or receive thousands of communications, publications, representations, statements, electronic transmissions and payments to carry-out the Opioid Marketing Enterprise's fraudulent scheme.

498. Because Purdue and its RICO Marketing Claim co-conspirators disguised their participation in the enterprise, and worked to keep even the enterprise's existence secret so as to give the false appearance that their false messages reflected the views of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to the books and records maintained by Purdue and its RICO Marketing Claim co-conspirators, Front Groups, and KOLs. Indeed, an essential part of the

successful operation of the Opioid Marketing Enterprise alleged herein depended upon secrecy. However, Plaintiffs have described the occasions on which Purdue and its RICO Marketing Claim co-conspirators, Front Groups, and KOLs disseminated misrepresentations and false statements to consumers, prescribers, regulators and Plaintiffs, and how those acts were in furtherance of the scheme.

499. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers, prescribers, regulators and Plaintiffs. Purdue and its RICO Marketing Claim co-conspirators, Front Groups and KOLs calculated and intentionally crafted the scheme and common purpose of the Opioid Marketing Enterprise to ensure their own profits remained high. In designing and implementing the scheme, Purdue and its RICO Marketing Claim co-conspirators understood and intended that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Purdue and its RICO Marketing Claim co-conspirators' products.

500. Purdue and its RICO Marketing Claim co-conspirators' pattern of racketeering activity alleged herein and the Opioid Marketing Enterprise are separate and distinct from each other. Likewise, Purdue and its RICO Marketing Claim co-conspirators are distinct from the Opioid Marketing Enterprise.

501. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

502. The racketeering activities conducted by Purdue and its RICO Marketing Claim co-conspirators, Front Groups and KOLs amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive consumers, prescribers, regulators and the Plaintiffs. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Purdue and its co-conspirators was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including consumers, prescribers, regulators and the Plaintiffs. Purdue and its RICO Marketing Claim co-conspirators have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the Opioid Marketing Enterprise.

503. Each of Purdue and its RICO Marketing Claim co-conspirators aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

504. As described herein, Purdue and its RICO Marketing Claim co-conspirators engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant money and revenue from the marketing and sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

505. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

506. Purdue and its RICO Marketing Claim co-conspirators' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiffs injury. Purdue and its RICO Marketing Claim co-conspirators' pattern of racketeering activity logically, substantially and foreseeably caused an opioid epidemic. Plaintiffs' injuries, as described below, were not unexpected, unforeseen or independent.<sup>162</sup> Rather, as Plaintiffs allege, Purdue and its RICO Marketing Claim co-conspirators knew that the opioids were unsuited to treatment of long-term chronic, nonacute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.<sup>217</sup> Nevertheless, Purdue and its RICO Marketing Claim co-conspirators engaged in a scheme of deception that utilized the mail and wires in order to carry-out the Opioid Marketing Enterprises' fraudulent scheme, thereby increasing sales of their opioid products.

507. It was foreseeable and expected that Purdue and its RICO Marketing Claim co-conspirators creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their fraudulent scheme would lead to a nationwide opioid epidemic, including increased opioid addiction and overdose.<sup>163</sup>

508. Specifically, Purdue and its RICO Marketing Claim co-conspirators' creating and then participating in the Opioid Marketing Enterprise through a pattern of racketeering activities to carry-out their scheme has injured Plaintiffs as they have a duty to care for NAS Children who require ongoing medical monitoring and surveillance, medical and developmental referral, provision of training and information for the Legal Guardians, and the convening and oversight of a Science Panel for purposes of epidemiological studies of the NAS Children at issue in this

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<sup>162</sup> *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5<sup>th</sup> 1026, 1030 (2017).

<sup>217</sup> *Id.* at 1041.

<sup>163</sup> *Id.*

Complaint so that the medical issues of the NAS Children may be properly addressed as they arise and exacerbate during the administration of the Science Panel. This abatement relief is all medically necessary and arises because Plaintiffs have an absolute duty of care for symptomatic NAS Children (over whom Plaintiffs also have dominion) and Plaintiffs were thereby injured as a result.

509. Plaintiffs' injuries were directly and thus proximately caused by Purdue and its co-conspirators' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic Purdue and its RICO Marketing Claim co-conspirators created through their Opioid Marketing Enterprise, Plaintiffs would not have been injured.

510. Plaintiffs seek all equitable and/or injunctive abatement relief as discussed herein as well as all other relief to which they have shown themselves justly entitled.<sup>164</sup>

511. Plaintiffs have been directly harmed in the exact same manner as the putative class members and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here on behalf of themselves and the putative class.

**B. Claim Two: Violation of RICO, 18 U.S.C. § 1961 et seq.—Opioid Supply Chain Enterprise**

512. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

513. At all relevant times, Purdue and its RICO Supply Chain co-conspirators<sup>165</sup> were and are "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

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<sup>164</sup> Alternatively, the Legal Guardians seek additional and further compensatory damages.

<sup>165</sup> Cephalon, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen

514. Purdue and its RICO Supply Chain Claim co-conspirators together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States. The Opioid Supply Chain Enterprise is an association-in-fact enterprise within the meaning of § 1961. The Opioid Supply Chain Enterprise consists of Purdue and its RICO Supply Chain Claim co-conspirators.

515. Purdue and its RICO Supply Chain Claim co-conspirators were members of the Healthcare Distribution Alliance (the “HDA”).<sup>166</sup> Each of Purdue and its RICO Supply Chain Claim co-conspirators is a member, participant, and/or sponsor of the HDA, and has been since at least 2006, and utilized the HDA to form the interpersonal relationships of the Opioid Supply Chain Enterprise and to assist them in engaging in the pattern of racketeering activity that gives rise to the Count.

516. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an existence separate and distinct from Purdue and its co-conspirators; (b) was separate and distinct from the pattern of racketeering in which they engaged; (c) was an ongoing and continuing organization consisting of legal entities, including Purdue and each of its co-conspirators; (d) was characterized by interpersonal relationships among Purdue and its RICO Supply Chain Claim co-conspirators; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit.. Each member of the Opioid Supply Chain Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid quotas and resulting sales.

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<sup>166</sup> *History*, Health Distribution Alliance,  
<https://www.healthcaredistribution.org/about/hdahistory> (last accessed Sept. 15, 2017).

517. Purdue and its RICO Supply Chain Claim co-conspirators carried out, or attempted to carry out, a scheme to defraud federal and state regulators, and the American public by knowingly conducting or participating in the conduct of the Opioid Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

518. Purdue and its RICO Supply Chain Claim co-conspirators committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that Purdue and its RICO Supply Chain Claim co-conspirators committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a “pattern of racketeering activity.” The racketeering activity was made possible by Purdue and its co-conspirators’ regular use of the facilities, services, distribution channels, and employees of the Opioid Supply Chain Enterprise. Purdue and its RICO Supply Chain Claim co-conspirators participated in the scheme to defraud by using mail, telephone and the Internet to transmit mailings and wires in interstate or foreign commerce.

519. Purdue and its RICO Supply Chain Claim co-conspirators also conducted and participated in the conduct of the affairs of the Opioid Supply Chain Enterprise through a pattern of racketeering activity by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

520. Purdue and its RICO Supply Chain Claim co-conspirators committed crimes that are punishable as felonies under the laws of the United States. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

521. Each of Purdue and its RICO Supply Chain Claim co-conspirators is a registrant as defined in the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

522. Purdue and its RICO Supply Chain Claim co-conspirators' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

- a. Mail Fraud: Purdue and its RICO Supply Chain Claim co-conspirators violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises, and omissions.
- b. Wire Fraud: Purdue and its RICO Supply Chain Claim co-conspirators violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription

opioids by means of false pretenses, misrepresentations, promises, and omissions.

523. Controlled Substance Violations: Purdue and its RICO Supply Chain Claim co-conspirators violated 21 U.S.C. § 823 by knowingly or intentionally furnishing false or fraudulent information in, and/or omitting material information from, documents filed with the DEA.

524. Purdue and its RICO Supply Chain Claim co-conspirators conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

525. Purdue and its RICO Supply Chain Claim co-conspirators aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

526. Purdue and its RICO Supply Chain Claim co-conspirators hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers and governmental entities about the reality of the suspicious orders that Purdue and its RICO Supply Chain Claim co-conspirators were filling on a daily basis – leading to the diversion of hundreds of millions of doses of prescriptions opioids into the illicit market.

527. Purdue and its RICO Supply Chain Claim co-conspirators, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

528. Indeed, for Purdue and its co-conspirators' fraudulent scheme to work, each of Purdue and its co-conspirators had to agree to implement similar tactics regarding manufacturing prescription opioids and refusing to report suspicious orders.

529. As described herein, Purdue and its RICO Supply Chain Claim co-conspirators engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

530. The predicate acts all had the purpose of creating the opioid epidemic that substantially injured Plaintiffs, while simultaneously generating billions of dollars of revenue and profits for Purdue and its RICO Supply Chain Claim co-conspirators. The predicate acts were committed or caused to be committed by Purdue and its RICO Supply Chain Claim co-conspirators through their participation in the Opioid Supply Chain Enterprise and in furtherance of its fraudulent scheme.

531. The pattern of racketeering activity alleged herein and the Opioid Supply Chain Enterprise are separate and distinct from each other. Likewise, Purdue and its RICO Supply Chain Claim co-conspirators are distinct from the enterprise.

532. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

533. Many of the precise dates of Purdue and its RICO Supply Chain Claim co-conspirators' criminal actions at issue here have been hidden by Purdue and its co-conspirators and cannot be alleged without access to Purdue and its co-conspirators' books and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain Enterprise alleged herein depended upon secrecy.

534. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Purdue and its co-conspirators engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

535. It was foreseeable to Purdue and its RICO Supply Chain Claim co-conspirators that Plaintiffs would be harmed when they refused to report and halt suspicious orders, because their violation of the duties imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of prescription opioids out of appropriate medical channels and into the illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

536. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

537. Purdue and its RICO Supply Chain Claim co-conspirators' violations of law and their pattern of racketeering activity directly and proximately caused injury to Plaintiffs, the members of the putative class, and the NAS Children. Purdue and its RICO Supply Chain Claim co-conspirators' pattern of racketeering activity, including their refusal to identify, report and halt suspicious orders of controlled substances, logically, substantially and foreseeably caused an opioid epidemic and skyrocketing rates of NAS. Plaintiffs, the members of the putative class, and the NAS Children were injured by Purdue and its RICO Supply Chain Claim co-conspirators' pattern of racketeering activity and the opioid epidemic that they created.

538. Purdue and its RICO Supply Chain Claim co-conspirators knew that the opioids they manufactured and supplied were unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids were highly addictive and subject to abuse.<sup>167</sup> Nevertheless, Purdue and its RICO Supply Chain Claim co-

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<sup>167</sup> *Travelers Prop. Cas. Co. of Am. v. Actavis, Inc.*, 16 Cal. App. 5<sup>th</sup> 1026, 1030 (2017).

conspirators engaged in a scheme of deception, that utilized the mail and wires as part of their fraud, in order to increase sales of their opioid products by refusing to identify, report suspicious orders of prescription opioids that they knew were highly addictive, subject to abuse, and were actually being diverted into the illegal market.<sup>168</sup>

539. Purdue and its RICO Supply Chain Claim co-conspirators' predicate acts and pattern of racketeering activity creating and then participating in the Opioid Supply Chain Enterprise through a pattern of racketeering activities to carry-out their scheme has injured Plaintiffs as they have a duty to care for NAS Children who require ongoing medical monitoring and surveillance, medical and developmental referral, provision of training and information for the Legal Guardians, and the convening and oversight of a Science Panel for purposes of epidemiological studies of the NAS Children at issue in this Complaint so that the medical issues of the NAS Children may be properly addressed as they arise and exacerbate during the administration of the Science Panel. This abatement relief is all medically necessary and arises because Plaintiffs have an absolute duty of care for symptomatic NAS Children (over whom Plaintiffs also have dominion) and Plaintiffs were thereby injured as a result.

540. Plaintiffs' injuries were directly and thus proximately caused by Purdue and its co-conspirators' racketeering activities because they were the logical, substantial and foreseeable cause of Plaintiffs' injuries. But for the opioid-addiction epidemic Purdue and its RICO Marketing Claim co-conspirators created through their Opioid Marketing Enterprise, Plaintiffs would not have been injured.

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<sup>168</sup> *City of Everett v. Purdue Pharma L.P.*, Case No. 17-cv-00209, 2017 WL 4236062, \*2 (W.D. Wash. Sept. 25, 2017).

541. Plaintiffs seek all equitable and/or injunctive abatement relief as discussed herein.<sup>169</sup>

542. Plaintiffs have been directly harmed in the exact same manner as the putative class members and there are no other Plaintiffs better suited to seek a remedy for the economic harms at issue here on behalf of themselves and the putative class.

**C. Claim Three: Negligence**

543. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

544. As Legal Guardians, Plaintiffs and the Putative Class Members owe immense, nearly unlimited, and non-delegable duties of care to protect the health and welfare of the NAS Children. An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's duty of care owed to the NAS Children, as well as the Legal Guardian's dominion over the NAS Children. Injury to the Legal Guardians by Purdue and its co-conspirators was both direct and entirely foreseeable because of the known health risks to birth mothers, the known risks of NAS to the infants they carried, and the known adverse impact and increased burden on the ability of the Legal Guardians to care for the NAS Children after birth.

545. Purdue and its co-conspirators owe a non-delegable duty to the Legal Guardian Plaintiffs and the Putative Class Members to conform their behavior to the legal standard of reasonable conduct under the circumstances, in the light of the apparent risks.

546. There is no social value to Purdue and its co-conspirators' challenged behavior. In fact, Purdue and its co-conspirators' entire conduct, behavior, actions, misrepresentations, conspiracies, and omissions are against the law.

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<sup>169</sup> Alternatively, the Legal Guardians seek additional and further compensatory damages.

547. On the other hand, there is immense social value to the interests threatened by Purdue and its co-conspirators' behavior, namely the health, safety, and welfare of the NAS Children in the care of the Legal Guardian Plaintiffs and the Putative Class Members.

548. Debtor Defendant Purdue and its co-conspirators' behavior caused a substantial injury and damage to the Legal Guardian Plaintiffs and the Putative Class Members who care for the NAS Children.

549. Debtor Defendant Purdue and its co-conspirators' conduct fell below the reasonable standard of care and was negligent. Their negligent acts include:

- a. Consciously supplying the U.S. market with highly addictive prescription opioids, including misrepresenting, understating, or obfuscating the highly addictive propensities of opioid pills;
- b. Using unsafe marketing, labeling, distribution, and dispensing practices, including failing to warn or advise physicians to conduct an family addiction history of each and every potential patient;
- c. Affirmatively enhancing the risk of harm from prescription opioids by failing to act as a last line of defense against diversion;
- d. Failing to properly train or investigate their employees;
- e. Failing to properly review and analyze prescription orders and data for red flags;
- f. Failing to report suspicious orders or refuse to fill them;
- g. Failing to provide effective controls and procedures to detect and/or guard against theft and diversion of controlled substances;
- h. Failing to police the integrity of their supply chains; and

- i. Creating misleading information with the intention of having prescribing physicians rely upon it.

550. Debtor Defendant Purdue separately, and/or in concert with its co-conspirators, each had an ability to control the opioids at a time when it knew or should have known it was passing control of the opioids to an actor further down in the supply chain that was incompetent or acting illegally and should not be entrusted with the opioids.

551. Debtor Defendant Purdue separately, and/or in concert with its co-conspirators each sold and/or distributed prescription opioids in the supply chain knowing (1) there was a substantial likelihood many of the sales were for non-medical purposes, (2) opioids are an inherently dangerous product when used for non-medical purposes, and (3) that every patient, before being prescribed even one opioid pill, needed to have a complete family history of addiction to alcohol and drugs, with any such history as a contraindication of any opioid use.

552. Debtor Defendant Purdue separately and/or in concert with its co-conspirators were negligent or reckless in not acquiring and utilizing special knowledge and special skills that relate to the dangerous activity in order to prevent or ameliorate such distinctive and significant dangers.

553. Controlled substances are dangerous commodities. Debtor Defendant Purdue separately, and/or in concert with its co-conspirators, breached the duty to exercise the degree of care, prudence, watchfulness, and vigilance commensurate with the dangers involved in the transaction of their business.

554. Debtor Defendant Purdue, separately and/or in concert with its co-conspirators, was also negligent or reckless in failing to guard against foreseeable third-party misconduct, e.g., the foreseeable conduct of: corrupt prescribers, corrupt pharmacists and staff, and/or criminals who buy and sell opioids for non-medical purposes.

555. Debtor Defendant Purdue and its co-conspirators are in a limited class of registrants authorized to legally distribute controlled substances. This places them in a position of great trust and responsibility vis-a-vis Legal Guardian Plaintiff(s) the Putative Class Members Plaintiffs, and the Class. Purdue and its co-conspirators owe a special duty to the Legal Guardian Plaintiff(s), and the Putative Class Members who care for the NAS Children. That duty cannot be delegated to another party.

556. The NAS Children are without fault.

557. The injuries to the NAS Children would not have happened in the ordinary course of events if Debtor Defendant Purdue separately, and/or in concert with its co-conspirators, used due care commensurate to the dangers involved in the distribution and dispensing of controlled substances.

558. Debtor Defendant Purdue separately, and/or in concert with its co-conspirators, owed a duty to prevent the exposure of the NAS Children to opioids, whether through a prescription to their birth mother or through the existence of the illegal secondary, diversionary market to which birth mothers had access. As to the diversionary, market, the Debtor Defendant Purdue and the Manufacturers were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint. *See* 21 U.S.C. § 823(a). The purpose of registration is the

***maintenance of effective controls against diversion of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under***

**adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.**<sup>170</sup>

559. Additionally, as “registrants” under Section 823, the Debtor Defendant Purdue and its RICO Marketing Claim co-conspirators were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. *See also* 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21 C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act” (21 U.S.C. 823 or 958)).

560. Similarly, and of equal importance, Purdue and its RICO Supply Chain Claim co-conspirators were required to register with the DEA, pursuant to the federal Controlled Substance Act.<sup>171</sup> Each Distributor and Pharmacies is a “registrant” as a wholesale distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”<sup>172</sup> Federal regulations impose a *non-delegable duty* upon wholesale drug distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration

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<sup>170</sup> 21 U.S.C. § 823(a)(1) (emphasis added).

<sup>171</sup> *See* 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100.

<sup>172</sup> 21 U.S.C. § 823(b)(1).

in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>173</sup>

561. In addition to reporting all suspicious orders, Purdue and its RICO Supply Chain Co-conspirators were also required to affirmatively stop shipment on any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels. Regardless, all flagged orders must be reported.

562. Debtor Defendant Purdue separately, and/or in concert with its co-conspirators, breached of each of the aforementioned duties resulted in a foreseeable harm to Plaintiffs and the putative class.

563. The aforementioned conduct of Debtor Defendant Purdue separately, and/or in concert with Manufacturers, Distributors, and Pharmacies proximately caused damage to the Legal Guardian Plaintiffs and the Putative Class Members who care for the NAS Children.

**D. Claim Four: Negligence Per Se**

564. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

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<sup>173</sup> 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b)

565. Debtor Defendant Purdue separately and/or in concert with the RICO Supply Chain Claim co-conspirators owed non-delegable statutory duties to Plaintiffs and the class. These duties were established to prevent the specific type of harm of which Plaintiffs suffered. Debtor Defendant Purdue separately and/or in concert with Purdue and its RICO Supply Chain Claim co-conspirators had a duty to prevent the diversion of the drugs which harmed Plaintiffs and the class members. The Debtor Defendant Purdue and the RICO Marketing Claim co-conspirators were required to register with the DEA to manufacture Schedule II Controlled Substances, including the opioids made the subject of this complaint.<sup>174</sup> The purpose of registration is the “maintenance of *effective controls against diversion* of particular controlled substances and any controlled substance in schedule I or II compounded therefrom into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes.”<sup>175</sup> Additionally, as “registrants” under Section 823, the Debtor Defendant Purdue and the RICO Marketing Claim co-conspirators were also required to monitor, report, and prevent suspicious orders of controlled substances via this process:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. 21 C.F.R. § 1301.74. See also 21 C.F.R. § 1301.02 (“Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.”); 21

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<sup>174</sup> See 21 U.S.C. § 823(a).

<sup>175</sup> 21 U.S.C. § 823(a)(1) (emphasis added).

C.F.R. § 1300.01 (“Registrant means any person who is registered pursuant to either section 303 or section 1008 of the Act” (21 U.S.C. 823 or 958)).<sup>176</sup>

566. Similarly, and of equal importance, each RICO Supply Chain Claim co-conspirator was also required to register with the DEA, pursuant to the federal Controlled Substance Act.<sup>177</sup> Each is a “registrant” as a distributor in the chain of distribution of Schedule II controlled substances with a duty to comply with all security requirements imposed under that statutory scheme. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain “effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels.”<sup>178</sup> As with the Debtor Defendant Purdue and the RICO Marketing Claim co-conspirators, federal regulations impose a *non-delegable duty* upon distributors to “design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”<sup>179</sup>

567. In addition to reporting all suspicious orders, registrants must also *affirmatively*

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<sup>176</sup> *Id.*

<sup>177</sup> See 21 U.S.C. § 823(b) and (e); 28 C.F.R. § 0.100.

<sup>178</sup> 21 U.S.C. § 823(b)(1).

<sup>179</sup> 21 C.F.R. § 1301.74(b). These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a wholesale distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor’s responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the wholesale distributor’s customer base and the patterns throughout the relevant segment of the wholesale distributor industry. 21 C.F.R. § 1301.74(b).

*stop shipment on any order which is flagged as suspicious* and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.<sup>180</sup> Regardless, all flagged orders must be reported.<sup>181</sup>

568. The harms caused to Plaintiffs and the class members were a direct and foreseeable result of Debtor Defendant Purdue separately, and/or in concert with Purdue and its RICO Marketing Claim and RICO Supply Chain Claim co-conspirators' breach of their statutory duties.

**E. Claim Five: Civil Conspiracy**

569. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

570. As Legal Guardians, Plaintiffs and the Putative Class Members owe immense, nearly unlimited, and non-delegable duties of care to protect the health and welfare of the NAS Children. An injury to the child is necessarily an injury to the Legal Guardian as a result of the Legal Guardian's duty of care owed to the NAS Children, as well as the Legal Guardian's dominion over the NAS Children. Having plead the commission of torts, Plaintiffs further plead that such torts occurred as part of a civil conspiracy. Debtor Defendant Purdue in concert engaged in civil conspiracy arising out of torts as to the Plaintiffs and the Putative Class Members via: (1) a malicious combination; (2) of two or more entities; (3) to injure another person or property; and (4) the existence of the unlawful acts discussed herein which were independent from the actual conspiracy. This civil conspiracy was a direct and proximate cause of harm to Plaintiffs, the

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<sup>180</sup> See *Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017).

<sup>181</sup> *Id.*

members of the putative class, and the NAS Children, and they were injured as a result and have sustained on-going damages which must be abated.

**F. Claim Five: Violations of New York General Business Law §§ 349 and 350**

571. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

572. The deceptive acts and practices (which include material omissions) of Purdue and its co-conspirators detailed herein, which includes but is not limited to the false advertising and marketing described in extensive detail, occurred in the conduct of business, trade, and/or commerce were unlawful under New York Gen. Bus. Law §§ 349 and 350 and were a direct and proximate cause of harm to Plaintiffs, the putative class members, and the NAS Children, and they were injured as a result and have sustained on-going damages which must be abated.

573. Purdue's act were perpetrated wantonly, recklessly, and with extreme disregard for Plaintiff Legal Guardians and the members of the putative class.

**G. Claim Six: Medical Monitoring and Surveillance**

574. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

575. As in independent tort, not just a claim for relief, Plaintiffs allege a claim for medical monitoring and surveillance in order to discharge their underlying duty of care for the symptomatic NAS Children. The NAS Children made the subject of this lawsuit were all medically diagnosed at or near birth with NAS and necessarily had significant exposure, such that the requested monitoring and surveillance is a reasonably certain consequence of their *in utero* exposure to opioids. The NAS Children all necessarily suffered subcellular or other physiological changes, as well as manifest physical or mental injury or disease.

576. The opioids to which the NAS Children were exposed *in utero* were toxic, proven hazardous substances, and are known to cause serious harm for which the NAS Children are at risk. As a result of this exposure, they have a relative increased risk in disease and injury, including additional increased risk of serious latent disease beyond the NAS for which they have already been diagnosed. Monitoring for the effects of the existing and latent disease and injury, including but not limited to periodic diagnostic medical exams, is medically reasonable and necessary according to contemporary and developing scientific principles. This monitoring and surveillance is different from that normally recommended in the absence of exposure, and is different from normal and routine pediatric medical care. Finally, there is clinical value in early detection and diagnosis for the specific disease and injury for which the NAS Children are at risk.

577. The requirement that there be medical monitoring and surveillance of the NAS Children was caused by Purdue's and its co-conspirators' bad acts which were a direct and proximate cause of harm to Plaintiffs, the members of the putative class, and the NAS Children, and they were injured as a result and have sustained on-going damages which must be abated.

578. Further, this is a rapidly transforming field, as multiple members of childcare, psychological, and medical personnel are coming together to determine the best protocols for improving outcomes after a diagnosis. *Hence, there is an absolute necessity that this Court convene a Science Panel.*

579. Regarding the necessity and scope of the abatement monitoring and surveillance protocol and need for a Science Panel, Plaintiffs submit the Affidavit of their expert Dr. Kanwaljeet ("Sunny") S. Anand, Professor of Pediatrics, Anesthesiology, Perioperative & Pain Medicine at Stanford University School of Medicine which is attached as Exhibit A and incorporated by reference.

**IX. ABATEMENT RELIEF AND ALTERNATIVE COMPENSATORY DAMAGES SOUGHT**

580. Plaintiffs repeat, re-allege, and incorporate by reference each and every allegation set forth above as if fully set forth herein.

581. the allegations in the foregoing paragraphs as if fully set out herein.

582. Plaintiff Legal Guardians and the Putative Class Members have a duty of care for the welfare of NAS Children who were exposed to opioids, a known toxic substance, at a concentration higher than expected for the general population and who suffer the physical injury of NAS.

583. The NAS Children in the care of Plaintiff Legal Guardians and the Putative Class Members face a lifetime of latent, dreaded medical and developmental conditions proven to be linked to *in utero* exposure to opioids, including but not limited to: brain damage, muscular-skeletal developmental disorders, speech and language disorders, cognitive developmental disorders, psychiatric disorders, emotional development disorders, behavioral disorders and increased risk of addiction. These injuries and increased risks of disease are necessarily an injury to the Plaintiff Legal Guardians and the Putative Class Members as a result of their unlimited and nondelegable duty of care owed to the NAS Children.

584. In order to discharge their duty of care, Plaintiff Legal Guardians and the Putative Class Members are seeking the creation of a trust from bankruptcy proceeds for ongoing medical surveillance and monitoring of the NAS Children, medical and developmental referral and provision of training and information. Such relief will bring to light the onset of these medical and emotional conditions so that treatment and intervention may begin at the earliest point possible. Notably, *Plaintiff Legal Guardians do not seek the recovery of injunctive or declaratory relief arising from the normal and regular costs of caring for a child or for routine pediatric and*

*adolescent medical care; instead, they only seek abatement necessitated by the NAS diagnosis and underlying in utero opioid exposures of the NAS Children.*

585. In order to discharge their duty of care, Plaintiff Legal Guardians and the Putative Class Members must also demand that the abatement relief of include trust provisions which will allow for the creation of a Science Panel implemented for purposes of epidemiological studies of the NAS Children, which shall collect and analyze medical monitoring results so that other heretofore unrecognized latent, dread diseases that may be associated with *in utero* exposure may be identified and that the Legal Guardians and treating professionals may better care for NAS Children, as well as so that medical professionals engaged in the research and development of new treatment will have access to a broader universe of data. A fund for expenses for maintenance and administration of this Science Panel shall be created by and costs borne by Purdue. The costs, nature, and extent of epidemiology and actions of the Science Panel shall be subject to the provisions of the enabling trust.

586. The harm visited upon the NAS Children and the Class is irreparable.

587. Money damages will not suffice because efficacious relief requires that ***all*** similarly situated NAS Children and their Guardians be enrolled in a comprehensive and uniform monitoring and surveillance plan with the class-wide resulting data driven into the supervisory Science Panel so that it may study and inform itself according to scientific and medical principals which require robust data sets and then make care recommendations for the NAS Children as a result. There can be no Science Panel convened for a single NAS Child, and certainly no epidemiological studies from a data set of “1.” *This generation of Americans is not yet lost, but absent an abatement, it will be.* Because the necessary abatement relief can be delivered only on a classwide basis, it is impossible to predict with any certainty the costs of implementing such

monitoring and surveillance for each individual class member, nor would the necessary relief result because treatment and intervention protocols from epidemiological studies must develop from the comprehensive and robust data sets created from the protocols and then provided by the Science Panel to the medical research community and treating physicians with the goals of developing new treatments, interventions, and additional diagnostic tests.

### **PRAYER FOR RELIEF**

**WHEREFORE**, the Plaintiff Legal Guardians on behalf of themselves and the similarly situated Legal Guardian Putative Class Members respectfully request any and all relief, in equity and law, to which they have shown themselves to be justly entitled, including but limited to:

- A. The creation of an abatement Trust to benefit the Legal Guardians and the NAS Children in their care that will fund ongoing medical monitoring and surveillance of the NAS Children, medical and developmental referral, provision of training and information for the Legal Guardians, a nationwide registry for NAS Children, and the convening and oversight of a Science Panel for purposes of epidemiological studies of the NAS Children at issue in this Complaint so that the implications of the NAS Childrens' additional risk of disease and injury may be properly addressed during the administration of the Science Panel, all of which are medically necessary;<sup>182</sup>
- B. Disgorgement of profits and equitable relief to prevent unjust enrichment;
- C. Awarding attorneys' fees and costs incurred and expected to be incurred by Plaintiff Legal Guardians and the Putative Class Members.

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<sup>182</sup> Alternatively, Plaintiffs have plead a legal right to recovery of compensatory damages.

- D. In the unlikely event that the Court finds that compensatory legal damages are an adequate remedy at law, then Plaintiffs request such damages in the amount that they may show themselves justly entitled;
- E. Punitive and/or pecuniary damages, including any additional damages pursuant to Purdue's and its co-conspirator's violations of New York Bus. Law §§359 and 360, in the highest amount allowed by law;
- F. Awarding all other relief, at law or in equity, to Plaintiff Legal Guardians and the Putative Class Members have shown themselves to be justly entitled and which may be just and proper.

Plaintiffs seek a trial by jury for all counts so triable.

**DATED:** \_\_\_\_\_.

Respectfully submitted,

**DRAFT**

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